



# FEDERAL REGISTER

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

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 1000

[Docket No. AMS-DA-18-0096]

#### Federal Milk Marketing Orders— Amending the Class I Skim Milk Price Formula; Correction

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule; correction.

**SUMMARY:** On March 11, 2019, the Agricultural Marketing Service (AMS) published a revision to the Class I skim milk price formula for milk pooled under the Federal milk marketing order (FMMO) as required by the Agriculture Improvement Act of 2018. This document explains the May 1, 2019, effective date and makes two clarifying corrections to the final regulations.

**DATES:** Effective May 1, 2019.

**FOR FURTHER INFORMATION CONTACT:** Erin Taylor, Acting Director, Order Formulation and Enforcement Division, USDA/AMS/Dairy Program, STOP 0231, Room 2963, 1400 Independence Ave. SW, Washington, DC 20250-0231; telephone: (202) 720-7311; or email: [erin.taylor@usda.gov](mailto:erin.taylor@usda.gov).

**SUPPLEMENTARY INFORMATION:** On March 11, 2019, AMS published a final rule amending the Class I skim milk price formula for milk pooled under the FMMO program (84 FR 8590). The amendments will be effective May 1, 2019. For clarification, as a result of this rule, the amended Class I skim milk price formula will apply to milk pooled on and after May 1, 2019. Therefore, the amended formula will be reflected in the May Advanced Class I skim milk price announced April 17, 2019. The final regulatory text also contained an incorrect section reference to § 1000.51(b) instead of § 1005.51(b), and did not include a rounding instruction in the calculation. This document

provides technical corrections to the final regulations.

#### Federal Register Correction

■ Effective May 1, 2019, in rule document 2019-04347 at 84 FR 8590 in the issue of March 11, 2019, on page 8591, in the third column, in amendatory instruction 2, paragraph (b) is corrected to read as follows:

#### § 1000.50 [Corrected]

(b) *Class I skim milk price.* The Class I skim milk price per hundredweight shall be the adjusted Class I differential specified in § 1000.52, plus the adjustment to Class I prices specified in §§ 1005.51(b), 1006.51(b) and 1007.51(b) of this chapter, plus the simple average of the advanced pricing factors computed in paragraph (q)(1) and (2) of this section rounded to the nearest cent, plus \$0.74 per hundredweight.

Dated: March 28, 2019.

**Bruce Summers,**

*Administrator.*

[FR Doc. 2019-06335 Filed 4-1-19; 8:45 am]

**BILLING CODE 3410-02-P**

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Chapter I

[NRC-2018-0113]

#### Clarification of Export Reporting Requirements for Nuclear Facilities, Equipment, and Non-Nuclear Materials

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Regulatory issue summary; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing Regulatory Issue Summary (RIS) 2019-01, “Clarification of Export Reporting Requirements for Nuclear Facilities, Equipment, and Non-Nuclear Materials.” This RIS is intended to clarify the reporting requirements for certain exports of nuclear facilities, equipment, and non-nuclear materials. The NRC’s regulations state, in part, that licensees exporting nuclear facilities, equipment, and certain non-nuclear materials under a general or specific license during the previous quarter must submit reports by January 15, April 15, July 15, and October 15 of each year on

DOC/NRC Forms AP-M or AP 13, and associated forms. The RIS includes information relating to this reporting requirement and clarifies that the quarterly reporting requirement is in addition to, and not obviated by, the separate NRC annual reporting requirement in its regulations.

**DATES:** The RIS is available as of April 2, 2019.

**ADDRESSES:** Please refer to Docket ID NRC-2018-0113 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0113. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. This RIS is available under ADAMS Accession No. ML18269A254.

- *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.

- This RIS is also available on the NRC’s public website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/> (select “2018” and then select “2019-01”).

**FOR FURTHER INFORMATION CONTACT:** Andrea Jones, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-287-9072; email: [Andrea.Jones2@nrc.gov](mailto:Andrea.Jones2@nrc.gov).

**SUPPLEMENTARY INFORMATION:** The NRC published a notice of opportunity for public comment on this RIS in the **Federal Register** (83 FR 26611) on June 8, 2018. The agency received comments from one commenter. The staff considered all comments, which resulted in changes to the RIS. The evaluation of these comments and the resulting changes to the RIS are discussed in a publicly available memorandum in ADAMS under Accession No. ML18269A255. As noted in 83 FR 20858 (May 8, 2018), this document is being published in the Rules section of the **Federal Register** to comply with publication requirements under Title 1 of the *Code of Federal Regulations*, Chapter I.

Dated at Rockville, Maryland, this 28th day of March 2019.

For the Nuclear Regulatory Commission.

**Tara Inverso,**

*Chief, ROP Support and Generic Communications Branch, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation.*

[FR Doc. 2019-06373 Filed 4-1-19; 8:45 am]

**BILLING CODE 7590-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2017-0433; Product Identifier 2016-SW-078-AD; Amendment 39-19602; AD 2019-06-04]

RIN 2120-AA64

#### **Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters**

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for Bell Helicopter Textron Canada Limited (BHTC) Model 429 helicopters. This AD requires inspecting each main rotor pitch link rod end bearing assembly (bearing) for wear and play. This AD was prompted by reports of worn bearings. The actions of this AD are intended to prevent an unsafe condition on these products.

**DATES:** This AD is effective May 7, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of May 7, 2019.

**ADDRESSES:** For service information identified in this final rule, contact Bell Helicopter Textron Canada Limited,

12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0433.

#### **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-2017-0433; 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 AD, the Transport Canada AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

#### **FOR FURTHER INFORMATION CONTACT:**

David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email [david.hatfield@faa.gov](mailto:david.hatfield@faa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Discussion**

On March 8, 2018, at 83 FR 9818, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to BHTC Model 429 helicopters, serial numbers 57001 and larger, with a bearing part number (P/N) 429-010-433-101 or 429-010-433-103 installed. The NPRM proposed to require inspecting each bearing for wear and play. The AD was prompted by reports of worn bearings. The proposed requirements were intended to prevent a worn bearing, which could result in failure of a bearing, which could lead to reduced helicopter handling, damage to other components, and subsequent loss of helicopter control.

The NPRM was prompted by Canadian AD No. CF-2016-39, dated December 12, 2016 (Transport Canada AD CF-2016-39), issued by Transport Canada, which is the aviation authority

for Canada, to correct an unsafe condition for BHTC Model 429 helicopters, serial numbers 57001 and subsequent. Transport Canada advises of reports of worn bearings adversely affecting the helicopters' handling qualities. Transport Canada states the scheduled inspection interval of 12 months or 800 hours is not sufficient to detect and correct a worn bearing under the current wear rate. Additionally, according to Transport Canada, the combination of the blade weight, positioning of the swashplate, and the preload of elastomers can make bearing play difficult to detect during a preflight exterior check. Transport Canada determined it necessary to implement an inspection frequent enough to detect a worn bearing in order to prevent a bearing from failing, adversely affecting handling qualities, and damaging adjacent components. These conditions could lead to loss of control of the helicopter. Transport Canada AD CF-2016-39 therefore requires inspecting bearing P/N 429-010-433-101/-103 for play and potential wear and replacing it if necessary, within 30 days from the effective date of its AD and at subsequent intervals not to exceed 50 hours air time.

#### **Comments**

After our NPRM was published, we received a comment from one commenter.

#### **Request**

The commenter questioned the need for the proposed AD. The commenter stated that Bell Helicopter Alert Service Bulletin 429-11-03, which was issued in 2011, already requires inspections of the pitch link bearings.

We disagree. While an operator may incorporate the procedures in the Bell Helicopter Alert Service Bulletin into its maintenance program, not all operators are required to do so. In order for the corrective actions in the service information to become mandatory, and to correct the unsafe condition identified in the NPRM, the FAA must issue an AD.

#### **FAA's Determination**

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative, has notified us of the unsafe condition described in the Transport Canada AD. We are issuing this AD because we evaluated all information provided by Transport Canada, reviewed the relevant information, considered the comments

received, and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

#### Differences Between This AD and the EASA AD

This AD requires initially inspecting the bearing within 20 hours time-in-service, while the Transport Canada AD requires the initial inspection within 30 days.

#### Related Service Information Under 1 CFR Part 51

We reviewed Bell Helicopter Alert Service Bulletin 429–11–03, Revision A, dated January 13, 2015 (ASB), which specifies inspecting bearing P/N 429–010–433–101 and P/N 429–010–433–103 within 10 flight hours and every 50 hours thereafter for play and potential wear.

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

#### Costs of Compliance

We estimate that this AD affects 64 helicopters of U.S. Registry and that labor costs average \$85 per work-hour. Based on these estimates, we expect the following costs:

- Inspecting the bearing requires 2 work-hours and no parts for a cost of \$170 per helicopter and \$10,880 for the U.S. fleet per inspection cycle.
- Replacing a –101 bearing requires 1 work-hour and \$3,560 for parts for a cost of \$3,645 per bearing. Replacing a –103 bearing requires 1 work-hour and \$3,365 for parts for a cost of \$3,450 per bearing.

#### Authority for This Rulemaking

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

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

that is likely to exist or develop on helicopters identified in this rulemaking action.

#### Regulatory Findings

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

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

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

#### 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):

**2019–06–04 Bell Helicopter Textron Canada Limited:** Amendment 39–19602; Docket No. FAA–2017–0433; Product Identifier 2016–SW–078–AD.

#### (a) Applicability

This AD applies to Bell Helicopter Textron Canada Limited Model 429 helicopters, serial numbers 57001 and larger, with a main rotor pitch link rod end bearing assembly (bearing) part number (P/N) 429–010–433–101 or 429–010–433–103 installed, certificated in any category.

#### (b) Unsafe Condition

This AD defines the unsafe condition as a worn bearing. This condition could result in failure of a bearing, which could lead to reduced helicopter handling, damage to other components, and subsequent loss of helicopter control.

#### (c) Effective Date

This AD becomes effective May 7, 2019.

#### (d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

#### (e) Required Actions

Within 20 hours time-in-service (TIS) and thereafter at intervals not to exceed 50 hours TIS:

- (1) Inspect the upper and lower pitch link rod ends for axial and radial bearing play by rolling the bearings through all angles, paying particular attention to the areas depicted in Figure 1 of Bell Helicopter Alert Service Bulletin 429–11–03, Revision A, dated January 13, 2015.
- (2) If there is any play in a bearing, remove the pitch link assembly and perform a dimensional inspection of the axial and radial bearing play. Measure the play at the angle that results in the maximum amount of play. Replace the rod end assembly before further flight if bearing play exceeds 0.010 inch for axial direction or 0.005 inch for radial direction.

#### (f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

#### (g) Additional Information

The subject of this AD is addressed in Transport Canada AD No. CF–2016–39, dated December 12, 2016. You may view the Transport Canada AD on the internet at <http://www.regulations.gov> in Docket No. FAA–2017–0433.

#### (h) Subject

Joint Aircraft Service Component (JASC) Code: 6200, Main Rotor System.

#### (i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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 the AD specifies otherwise.

(i) Bell Helicopter Alert Service Bulletin 429-11-03, Revision A, dated January 13, 2015.

(ii) [Reserved]

(3) For Bell Helicopter Textron Canada service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437-2862 or (800) 363-8023; fax (450) 433-0272; or at <http://www.bellcustomer.com/files/>.

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(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, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on March 15, 2019.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2019-06018 Filed 4-1-19; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2017-1085; Product Identifier 2016-SW-094-AD; Amendment 39-19603; AD 2019-06-05]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

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

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for Airbus Helicopters Deutschland GmbH (Airbus Helicopters) Model MBB-BK 117 A-1, MBB-BK 117A-3, MBB-BK 117 A-4, MBB-BK 117 B-1, MBB-BK 117 B-2, MBB-BK 117 C-1, and MBB-BK 117 C-2 helicopters. This AD requires repetitive inspections of the tail rotor (T/R) gearbox housing. This AD was prompted by a report that a crack was found in a T/R gearbox housing. The actions of this AD are intended to correct an unsafe condition on these products.

**DATES:** This AD is effective May 7, 2019.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of May 7, 2019.

**ADDRESSES:** For service information identified in this final rule, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at [http://www.helicopters.airbus.com/website/en/ref/Technical-Support\\_73.html](http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html). You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-1085.

#### 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-2017-1085; 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 AD, the European Aviation Safety Agency (EASA) AD, any incorporated-by-reference service information, the economic evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

#### FOR FURTHER INFORMATION CONTACT:

David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email [david.hatfield@faa.gov](mailto:david.hatfield@faa.gov).

#### SUPPLEMENTARY INFORMATION:

#### Discussion

On September 10, 2018, at 83 FR 45578, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Airbus Helicopters Model MBB-BK 117 A-1, MBB-BK 117A-3, MBB-BK 117 A-4, MBB-BK 117 B-1, MBB-BK 117 B-2, MBB-BK 117 C-1, and MBB-BK 117 C-2 helicopters. The NPRM proposed to require a repetitive cleaning and visual inspection of the T/R gearbox housing for a crack, and replacing the T/R gearbox if there is a crack. The proposed

requirements were intended to detect a crack in a T/R gearbox housing, which could result in the loss of the T/R gearbox and subsequent loss of helicopter control.

The NPRM was prompted by EASA AD No. 2016-0134, dated July 8, 2016, issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for Airbus Helicopters Model MBB-BK 117 A-1, MBB-BK 117 A-3, MBB-BK 117 A-4, MBB-BK 117 B-1, MBB-BK 117 B-2, MBB-BK 117 C-1, MBB BK 117 C-2, and MBB-BK 117 C-2e helicopters. EASA advises that a crack was found in the T/R gearbox housing of a Model MBB-BK117 C-2 helicopter. According to EASA, investigations determined high vibrations caused by T/R imbalance were a contributing factor to the crack. EASA states that this condition, if not detected and corrected, could lead to the loss of the T/R gearbox and subsequent loss of control of the helicopter. As a result, the EASA AD requires repetitive inspections of the T/R gearbox housing and replacing the housing if a crack is found.

#### Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

#### FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to our bilateral agreement with the European Union, EASA has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

#### Differences Between This AD and the EASA AD

The EASA AD applies to Model MBB-BK117 C-2e helicopters, and this AD does not because it is not an FAA type-certificated model. The EASA AD allows a non-cumulative tolerance of 10 hours time-in-service for the inspections, and this AD does not. The EASA AD requires performing the inspection after a certain maintenance action and before a T/R gearbox housing is installed, and this AD does not.

### Related Service Information Under 1 CFR Part 51

We reviewed Airbus Helicopters Alert Service Bulletin (ASB) MBB-BK117-30A-119, Revision 0, dated May 24, 2016, for Model MBB-BK 117 A-1, MBB-BK 117 A-3, MBB-BK 117 A-4, MBB-BK 117 B-1, MBB-BK 117 B-2, and MBB-BK 117 C-1 helicopters and ASB MBB-BK117 C-2-65A-007, Revision 0, dated May 24, 2016, for MBB-BK 117 C-2 helicopters. This service information specifies an initial and repetitive inspections of the T/R gearbox housing for cracks.

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

### Costs of Compliance

We estimate that this AD affects 176 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at \$85 per work-hour.

Inspecting the T/R gearbox requires 1 work-hour for an estimated cost of \$85 per helicopter and \$14,960 for the U.S. fleet per inspection cycle. Replacing the T/R gearbox requires 4.5 work-hours and parts cost \$69,219 for an estimated cost of \$69,602 per helicopter.

### Authority for This Rulemaking

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

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

### Regulatory Findings

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

responsibilities among the various levels of government.

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

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

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

### 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):

#### 2019-06-05 Airbus Helicopters

**Deutschland GmbH:** Amendment 39-19603; Docket No. FAA-2017-1085; Product Identifier 2016-SW-094-AD.

#### (a) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH Model MBB-BK 117 A-1, MBB-BK 117 A-3, MBB-BK 117 A-4, MBB-BK 117 B-1, MBB-BK 117 B-2, MBB-BK 117 C-1, and MBB-BK 117 C-2 helicopters, certificated in any category.

#### (b) Unsafe Condition

This AD defines the unsafe condition as a crack in a tail rotor (T/R) gearbox housing. This condition could result in the loss of the T/R gearbox and subsequent loss of helicopter control.

#### (c) Effective Date

This AD becomes effective May 7, 2019.

#### (d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

### (e) Required Actions

Within 100 hours time-in-service (TIS) and thereafter at intervals not to exceed 100 hours TIS, clean and visually inspect the T/R gearbox housing for a crack in the area depicted in Figure 1 of Airbus Helicopters Alert Service Bulletin (ASB) MBB-BK117-30A-119, Revision 0, dated May 24, 2016, or ASB MBB-BK117 C-2-65A-007, Revision 0, dated May 24, 2016, as applicable to your model helicopter. If there is a crack, replace the T/R gearbox before further flight.

### (f) Special Flight Permits

Special flight permits are prohibited.

### (g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

### (h) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2016-0134, dated July 8, 2016. You may view the EASA AD on the internet at <http://www.regulations.gov> in Docket No. FAA-2017-1085.

### (i) Subject

Joint Aircraft Service Component (JASC) Code: 6520, Tail Rotor Gearbox.

### (j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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 the AD specifies otherwise.

(i) Airbus Helicopters Alert Service Bulletin (ASB) MBB-BK117-30A-119, Revision 0, dated May 24, 2016.

(ii) Airbus Helicopters ASB MBB-BK117 C-2-65A-007, Revision 0, dated May 24, 2016.

(3) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at [http://www.helicopters.airbus.com/website/en/ref/Technical-Support\\_73.html](http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html).

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For

information on the availability of this material at the FAA, call (817) 222-5110.

(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, call (202) 741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Fort Worth, Texas, on March 20, 2019.

**Lance T. Gant,**

*Director, Compliance & Airworthiness Division, Aircraft Certification Service.*

[FR Doc. 2019-06022 Filed 4-1-19; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 95**

[Docket No. 31246; Amdt. No. 545]

**IFR Altitudes; Miscellaneous Amendments**

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

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

**DATES:** 0901 UTC, April 25, 2019.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. Nichols, Flight Procedures

and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg 29, Room 104, Oklahoma City, OK 73125. Telephone: (405) 954-4164.

**SUPPLEMENTARY INFORMATION:** This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

**The Rule**

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and

contrary to the public interest and that, good cause exists for making the amendment effective in less than 30 days.

**Conclusion**

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 95**

Airspace, Navigation (air).

Issued in Washington, DC, on March 22, 2019.

**Rick Domingo,**

*Executive Director, Flight Standards Service.*

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, April 25, 2019.

■ 1. The authority citation for part 95 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

■ 2. Part 95 is amended to read as follows:

**REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT**

[Amendment 545 Effective Date April 25, 2019]

From	To	MEA	MAA
<b>§ 95.3000 Low Altitude RNAV Routes</b>			
<b>§ 95.3273 RNAV Route T273 Is Amended To Read in Part</b>			
AYKID, AK FIX .....	TUVVO, AK FIX .....	6400	17500
From	To	MEA	
<b>§ 95.6001 Victor Routes—U.S.</b>			
<b>§ 95.6014 VOR Federal Airway V14 Is Amended To Read in Part</b>			
CHISUM, NM VORTAC .....	ONSOM, NM FIX .....	.....	
*6000—MOCA .....	W BND .....	*7000	
	E BND .....	*7500	
LUBBOCK, TX VORTAC .....	CHILDRRESS, TX VORTAC .....	5100	

From	To	MEA
<b>§ 95.6044 VOR Federal Airway V44 Is Amended To Read in Part</b>		
SEA ISLE, NJ VORTAC ..... *7000—MCA KARRS, NJ FIX, NE BND. **1800—MOCA. **2000—GNSS MEA.	*KARRS, NJ FIX .....	**6000
KARRS, NJ FIX ..... *1300—MOCA. *2500—GNSS MEA.	GAMBY, NJ FIX .....	*7000
GAMBY, NJ FIX ..... *1600—MOCA. *2500—GNSS MEA.	DEER PARK, NY VOR/DME .....	*5000
<b>§ 95.6063 VOR Federal Airway V63 Is Amended To Read in Part</b>		
BURLINGTON, IA VOR/DME .....	MOLINE, IL VOR/DME .....	3100
MOLINE, IL VOR/DME .....	DAVENPORT, IA VORTAC .....	3100
<b>§ 95.6068 VOR Federal Airway V68 Is Amended To Read in Part</b>		
CHISUM, NM VORTAC .....	HAGER, NM FIX. W BND ..... E BND .....	6000 6500
<b>§ 95.6078 VOR Federal Airway V78 Is Amended To Read in Part</b>		
IRON MOUNTAIN, MI VOR/DME .....	VUKFI, MI FIX .....	3300
VUKFI, MI FIX ..... *2300—MOCA.	ESCANABA, MI VOR/DME .....	*3000
<b>§ 95.6148 VOR Federal Airway V148 Is Amended To Read in Part</b>		
IRONWOOD, MI VOR/DME ..... *3200—MOCA.	HOUGHTON, MI VOR/DME .....	*3700
<b>§ 95.6175 VOR FEDERAL AIRWAY V175 Is Amended To Read in Part</b>		
MALDEN, MO VORTAC ..... *2700—MOCA.	BUNKS, MO FIX .....	*4000
BUNKS, MO FIX .....	VICHY, MO VOR/DME .....	3000
VICHY, MO VOR/DME ..... *2500—MOCA.	ZIPUR, MO FIX .....	*3000
ZIPUR, MO FIX .....	HALLSVILLE, MO VORTAC .....	2700
HALLSVILLE, MO VORTAC .....	MACON, MO VOR/DME .....	3100
*LINDE, IA FIX ..... *5500—MRA. **5500—MRA. ***3000—MOCA. *MADUP, IA FIX **WELTE, IA FIX 5500. *5500—MRA. **3900—MRA. *WELTE, IA FIX .....	**MADUP, IA FIX .....	***5500
*3900—MRA.	SIOUX CITY, IA VORTAC. W BND ..... E BND .....	3000 5500
REDWOOD FALLS, MN VOR/DME .....	ALEXANDRIA, MN VOR/DME .....	3600
ALEXANDRIA, MN VOR/DME .....	PARK RAPIDS, MN VOR/DME .....	3300
ROSEAU, MN VOR/DME ..... *2600—MOCA.	U.S. CANADIAN BORDER .....	*3600
<b>§ 95.6217 VOR Federal Airway V217 Is Amended To Read in Part</b>		
GREEN BAY, WI VORTAC .....	WISOM, WI FIX .....	2700
WISOM, WI FIX .....	RHINELANDER, WI VOR/DME .....	3600
<b>§ 95.6276 VOR Federal Airway V276 Is Amended To Read in Part</b>		
CASVI, NJ FIX ..... *6000—MCA GAMBY, NJ FIX, SE BND. **1500—MOCA.	*GAMBY, NJ FIX .....	**3000
GAMBY, NJ FIX ..... *8000—MRA. **2000—MOCA. **3000—GNSS MEA.	*PREPI, OA FIX .....	**6000

From		To	MEA	
<b>§ 95.6376 VOR Federal Airway V376 Is Amended To Read in Part</b>				
RICHMOND, VA VOR/DME ..... *3000—MCA GRUBY, VA FIX, N BND.		*GRUBY, VA FIX .....	2000	
GRUBY, VA FIX ..... *1700—MOCA.		IRONS, MD FIX .....	*4500	
<b>§ 95.6430 VOR Federal Airway V430 Is Amended To Read in Part</b>				
IRONWOOD, MI VOR/DME .....		DINER, MI FIX .....	3600	
DINER, MI FIX ..... *4000—GNSS MEA.		IRON MOUNTAIN, MI VOR/DME .....	*5000	
IRON MOUNTAIN, MI VOR/DME .....		VUKFI, MI FIX .....	3300	
VUKFI, MI FIX ..... *2300—MOCA.		ESCANABA, MI VOR/DME .....	*3000	
Airway Segment			Changeover Points	
From	To	Distance	From	
<b>§ 95.8003 VOR Federal Airway Changeover Point V376 Is Amended To Add Changeover Point</b>				
RICHMOND, VA VOR/DME .....		WASHINGTON, DC VOR/DME .....	53	RICHMOND

[FR Doc. 2019-06394 Filed 4-1-19; 8:45 am]  
BILLING CODE 4910-13-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 112, 117, and 507**

[Docket Nos. FDA-2011-N-0920, FDA-2011-N-0921, and FDA-2011-N-0922]

RIN 0910-AG10, 0910-AG35, and 0910-AG36

**Implementing the Food and Drug Administration Food Safety Modernization Act; Technical Amendment**

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

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

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is correcting with technical amendments two final rules that published in the **Federal Register** of September 17, 2015, and one final rule that published in the **Federal Register** of November 27, 2015. The final rules published with editorial and inadvertent errors. This document corrects those errors.

**DATES:** Effective April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Sylvia Kim, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7599.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 17, 2015 (80 FR 55908 and 80 FR 56170), FDA published the final rules “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” and “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” with editorial and inadvertent errors in the regulatory text. In the **Federal Register** of November 27, 2015 (80 FR 74354), FDA published the final rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” with editorial and inadvertent errors in the regulatory text. This action is being taken to correct those editorial and inadvertent errors.

**List of Subjects**

*21 CFR Part 112*

Foods, fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

*21 CFR Part 117*

Food packaging, Foods.

*21 CFR Part 507*

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

**PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION**

■ 1. The authority citation for part 112 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 112.4, revise paragraph (a) to read as follows:

**§ 112.4 Which farms are subject to the requirements of this part?**

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as “produce” is defined in § 112.3) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a “covered farm” subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

\* \* \* \* \*

■ 3. In § 112.5, revise paragraphs (a)(1) and (2) to read as follows:

**§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?**

(a) \* \* \*

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3) the farm sold directly to qualified end-users (as defined in § 112.3) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3) the farm sold during the 3-year period preceding the applicable calendar year

was less than \$500,000, adjusted for inflation.

\* \* \* \* \*

■ 4. In § 112.161, revise paragraph (b) to read as follows:

**§ 112.161 What general requirements apply to records required under this part?**

\* \* \* \* \*

(b) Records required under §§ 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

**PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD**

■ 5. The authority citation for part 117 continues to read as follows:

**Authority:** 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 6. In § 117.126, revise paragraph (b)(5) to read as follows:

**§ 117.126 Food safety plan.**

\* \* \* \* \*

(b) \* \* \*

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a);

\* \* \* \* \*

**PART 507—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS**

■ 7. The authority citation for part 507 continues to read as follows:

**Authority:** 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 8. In § 507.31, revise paragraph (c)(5) to read as follows:

**§ 507.31 Food safety plan.**

\* \* \* \* \*

(c) \* \* \*

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a);

\* \* \* \* \*

■ 9. In § 507.130, revise paragraph (c)(2)(ii) to read as follows:

**§ 507.130 Conducting supplier verification activities for raw materials and other ingredients.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety laws, including relevant laws and regulations of foreign countries.

\* \* \* \* \*

Dated: March 26, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06141 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510, 520, 522, 524, 528, 556, and 558**

[Docket No. FDA-2018-N-0002]

**New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship**

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

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

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2018. FDA is informing the public of the availability

of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to make technical amendments to improve the readability of the regulations.

**DATES:** This rule is effective April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, [george.haibel@fda.hhs.gov](mailto:george.haibel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Approval Actions**

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2018, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

**TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2018**

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 1, 2018	200-490	Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052.	Carprofen, Chewable Tablets.	Dogs .....	Original approval as a generic copy of NADA 141-111.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2018—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 15, 2018	141-485	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	Lincomycin and clopidol, Type C medicated feeds.	Chickens ...	Original approval for use of LINCOMIX (lincomycin) and COYDEN (clopidol) Type A medicated articles in the manufacture of Type C medicated broiler chicken feeds for the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin, and for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	FOI Summary.
November 1, 2018.	200-627	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.	Cyclosporine Capsules, USP MODIFIED.	Dogs .....	Original approval as a generic copy of NADA 141-218.	FOI Summary.
November 6, 2018.	141-508	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	EXPERIOR (lubabegron) Type A medicated article to be used in the manufacture of Type B and Type C medicated feeds.	Cattle .....	Original approval for reduction of ammonia gas emissions per pound of live weight and hot carcass weight in beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed.	FOI Summary EA/FONSI. <sup>1</sup>
November 9, 2018.	141-502	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	REVOLUTION PLUS (selamectin and sarolaner topical solution).	Cats .....	Original approval for the prevention of heartworm disease caused by <i>Dirofilaria immitis</i> . Kills adult fleas ( <i>Ctenocephalides felis</i> ) and is indicated for the treatment and prevention of flea infestations; the treatment and control of tick infestations with <i>Ixodes scapularis</i> (black-legged or deer tick), <i>Amblyomma maculatum</i> (Gulf Coast tick), and <i>Dermacentor variabilis</i> (American dog tick); the treatment and control of ear mite ( <i>Otodectes cynotis</i> ) infestations; and the treatment and control of roundworm ( <i>Toxocara cati</i> ) and intestinal hookworm ( <i>Ancylostoma tubaeforme</i> ) infections in cats and kittens 8 weeks of age and older, and weighing 2.8 pounds or greater.	FOI Summary.
November 21, 2018.	038-439	Phibro Animal Health, Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	TERRAMYCIN (oxytetracycline), Type A medicated article.	Salmonids	Supplemental approval for marking the skeletal tissue of freshwater-reared salmonids.	FOI Summary.
December 4, 2018.	141-509	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002.	PEXION (imepitoin tablets).	Dogs .....	Original approval for the treatment of noise aversion in dogs.	FOI Summary.
December 19, 2018.	200-629	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	MILBEGUARD (milbemycin oxime), Flavored Tablets.	Dogs and cats.	Original approval as a generic copy of NADA 140-915.	FOI Summary.
December 27, 2018.	141-511	LFB USA, Inc., 175 Crossing Blvd., Frammingham, MA 01702.	Bc2371 rDNA construct in R69 New Zealand white rabbits.	R69 New Zealand white rabbits.	Original approval for expression of a gene for recombinant human Factor VII (rhFVIIa) in R69 New Zealand white rabbits.	FOI Summary EA/FONSI. <sup>1</sup>

<sup>1</sup> The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

**II. Change of Sponsorship**

Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia,

Bulgaria, has informed FDA that it has transferred ownership of, and all rights and interest in, the following

applications to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.

File No.	Product name	21 CFR section
140-951 .....	CLINACOX (diclazuril) Type A Medicated Article .....	558.198
141-153 .....	CLINACOX (diclazuril)/BMD (bacitracin methylenedisalicylate) .....	558.198
141-158 .....	CLINACOX (diclazuril)/FLAVOMYCIN (bambermycins) .....	558.198
141-194 .....	CLINACOX (diclazuril)/BMD (bacitracin methylenedisalicylate) .....	558.198

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship.

**III. Technical Amendments**

We are reformatting the regulations in subpart B of part 558 for certain medicated feeds to present their approved conditions of use in the current tabular format. In addition, we are removing cross-referencing citations for indications for use of combination drug medicated feeds wherever they have been used and in their place are adding the full text of the indications. These actions are being taken to improve the consistency and readability of the regulations.

**IV. Legal Authority**

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of “notice[s] . . . effective as a regulation,” of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of

the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as “an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.”

**List of Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Parts 520, 522, 524, and 528*

Animal drugs.

*21 CFR Part 556*

Animal drugs, Foods.

*21 CFR Part 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, 528, 556, and 558 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), revise the entry for “AquaBounty Technologies, Inc.” and alphabetically add an entry for “Dragon Fire Holding Co., Inc.”; and in the table in paragraph (c)(2), numerically add an entry for “076033” and revise the entry for “086053” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

*	*	*	*	*
(c)	*	*	*	
(1)	*	*	*	

Firm name and address	Drug labeler code
* * * * *	
AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754 .....	086053
* * * * *	
Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052 .....	076033
* * * * *	

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	
076033 .....	Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052.
* * * * *	
086053 .....	AquaBounty Technologies, Inc., 2 Mill and Main Pl., Suite 395, Maynard, MA 01754.
* * * * *	

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 3. The authority citation for part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 520.304 [Amended]**

■ 4. In § 520.304, in paragraph (b)(1), remove “054771, 026637, 055529, and 062250” and in its place add “026637, 054771, 055529, 062250, and 076033”.

■ 5. In § 520.522, revise paragraph (b) to read as follows:

**§ 520.522 Cyclosporine.**

\* \* \* \* \*

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 058198 for use of products described in paragraph (a) as in paragraph (d) of this section.

(2) No. 026637 for use of product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

\* \* \* \* \*

■ 6. Add § 520.1150 to read as follows:

**§ 520.1150 Imepitoin.**

(a) *Specifications.* Each tablet contains 100 or 400 milligrams (mg) imepitoin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer orally twice daily, approximately 12 hours apart, at a dose of 13.6 mg per pound (30 mg/kg) of body weight. Initiate therapy starting 2 days prior to the day of the expected noise event and continuing through the noise event.

(2) *Indications for use.* For the treatment of noise aversion in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 7. Revise § 520.1441 to read as follows:

**§ 520.1441 Milbemycin.**

(a) *Specifications.* Each flavored tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams (mg) of milbemycin oxime.

(b) *Sponsors.* See Nos. 013744 and 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* For hookworm, roundworm, and whipworm, administer 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)). For heartworm, administer 0.05 mg/lb of body weight (0.1 mg/kg). Administer once a month.

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by *Toxocara canis* and *Toxascaris leonina* and whipworm infections caused by *Trichuris vulpis* in dogs and puppies 4 weeks of age or greater and 2 pounds body weight or greater.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount.* Administer 0.91 mg/lb of body weight (2.0 mg/kg) once a month.

(ii) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

■ 8. The authority citation for part 522 continues to read as follows:

*Authority:* 21 U.S.C. 360b.

■ 9. Amend § 522.1662a by adding two sentences at the end of paragraph (h)(3)(iii) to read as follows:

**§ 522.1662a Oxytetracycline hydrochloride injection.**

\* \* \* \* \*

(h) \* \* \*

(3) \* \* \*

(iii) \* \* \* A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

\* \* \* \* \*

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 10. The authority citation for part 524 continues to read as follows:

*Authority:* 21 U.S.C. 360b.

■ 11. Add § 524.2099 to read as follows:

**§ 524.2099 Selamectin and sarolaner.**

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) selamectin and 10 mg sarolaner. The drug is provided in single dose tubes containing 0.25, 0.5, or 1 mL of solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats—(1) Amount.* Administer 2.7 mg selamectin per pound (/lb) (6 mg per kilogram (/kg)) of body weight and 0.45 mg/lb sarolaner (1 mg/kg) by emptying the contents of the tube on the back of the animal at the base of the neck in front of the shoulder blades.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations; the treatment and control of tick infestations with *Ixodes scapularis* (black-legged or deer tick), *Amblyomma maculatum* (Gulf Coast tick), and *Dermacentor variabilis* (American dog tick); the treatment and control of ear mite (*Otodectes cynotis*) infestations; and the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma*

*tubaeforme*) infections in cats and kittens 8 weeks of age and older, and weighing 2.8 pounds or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS**

■ 12. The authority citation for part 528 continues to read as follows:

*Authority:* 21 U.S.C. 360b.

■ 13. Add § 528.1080 to read as follows:

**§ 528.1080 Bc2371 recombinant deoxyribonucleic acid construct.**

(a) *Specifications and intended use.* A single copy of Bc2371, a human Factor VII recombinant deoxyribonucleic acid (rDNA) gene construct, located on chromosome 3p1.1–2 in a diploid line (R69) of hemizygous and homozygous New Zealand white rabbits (*Oryctolagus cuniculus*).

(b) *Sponsor.* See No. 086047 in § 510.600 of this chapter.

(c) *Conditions of use—(1) Intended use.* The construct directs gene expression of recombinant human Factor VII (hFVII) in the mammary gland such that recombinant hFVII zymogen is present in the rabbit milk, enabling purification and activation of recombinant hFVIIa intended for the treatment of hemophilia A or B in humans with inhibitors to Factors VIII and IX.

(2) *Limitations.* Food or feed from R69 rabbits is not permitted in the food or feed supply.

**PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

■ 14. The authority citation for part 556 continues to read as follows:

*Authority:* 21 U.S.C. 342, 360b, 371.

■ 15. Add § 556.370 to subpart B to read as follows:

**§ 556.370 Lubabegron.**

(a) *Acceptable daily intake (ADI).* The ADI for total residues of lubabegron is 3 micrograms per kilogram of body weight per day.

(b) *Tolerance in cattle.* The tolerance for lubabegron (marker residue) is:

(1) *Cattle—Liver (target tissue):* 10 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.330 of this chapter.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

**§ 558.4 Requirement of a medicated feed mill license.**

■ 16. The authority citation for part 558 continues to read as follows:

■ 17. In § 558.4, in paragraph (d), in the “Category I” table, alphabetically add an entry for “Lubabegron” to read as follows:

\* \* \* \* \*  
(d) \* \* \*

**CATEGORY I**

Drug	Assay limits percent <sup>1</sup> Type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> Type B/C <sup>2</sup>
Lubabegron .....	87–107	908 g/ton .....	85–115/80–120

\* \* \* \* \*  
■ 18. In § 558.140, revise paragraphs (e)(1) and (2) to read as follows:

**§ 558.140 Chlortetracycline and sulfamethazine.**

(e) \* \* \*  
(1) *Cattle*—

Chlortetracycline and sulfamethazine amount	Indications for use	Limitations	Sponsors
(i) To provide 350 milligrams per head per day each, chlortetracycline and sulfamethazine.	Beef cattle: For aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.	Feed for 28 days; withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 069254
(ii) [Reserved]			

(2) *Swine*—

Chlortetracycline and sulfamethazine amount	Indications for use	Limitations	Sponsors
(i) 100 g/ton of feed each, chlortetracycline and sulfamethazine.	Swine: For reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by <i>Salmonella choleraesuis</i> and vibronic dysentery); prevention of these diseases during times of stress; and maintenance of weight gains in the presence of atrophic rhinitis.	Feed as the sole ration. Withdraw 15 days prior to slaughter.	054771 069254
(ii) [Reserved]			

\* \* \* \* \*  
■ 19. In § 558.175, revise paragraph (d) to read as follows:

**§ 558.175 Clopidol.**

\* \* \* \* \*  
(d) *Conditions of use*—(1) *Chickens*—

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 113.5 .....	.....	Broiler chickens and re-placement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	Do not feed to chickens over 16 weeks of age ...	016592
(ii) 113.5 .....	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for increased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592
(iii) 113.5 .....	Bacitracin zinc, 5 to 25 ..	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771 016592
(iv) 113.5 .....	Bambermycins, 1 to 2 ...	Broiler chickens: As an aid in prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age.	016592

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(v) 227 .....	.....	Broiler and replacement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	016592
(vi) 227 .....	Bambermycins, 1 to 2 ...	Broiler chickens: As an aid in prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> ; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration until 5 days before slaughter. Withdraw 5 days before slaughter or feed 113.5 g/ton clopidol and 1 to 2 g/ton bambermycins during those 5 days before slaughter. Do not feed to chickens over 16 weeks of age.	016592

(2) Turkeys—

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 113.5 or 227 .....	.....	Turkeys: As an aid in the prevention of leucocytozoonosis caused by <i>Leucocytozoon smithi</i> .	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.	016592
(ii) [Reserved]				

(3) Clopidol may also be used in combination with:

(i)–(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

■ 20. In § 558.195, revise paragraphs (e)(1) through (3) to read as follows:

**§ 558.195 Decoquinatē.**

\* \* \* \* \*

(e) \* \* \*

(1) Chickens—

Decoquinatē in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2 .....		Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> .	Do not feed to laying hens producing eggs for human consumption.	054771
(ii) 27.2 .....	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> ; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 27.2 .....	Bacitracin zinc, 10 to 50	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> .	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(2) Cattle—

Decoquinatē in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8 .....		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for human consumption. See paragraph (d)(3) of this section.	054771
(ii) 12.9 to 90.8 .....	Monensin, 5 to 30 .....	Cattle fed in confinement for slaughter: For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for improved feed efficiency.	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinatē per 100 lb of body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and § 558.355(d)(9)(i). Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	054771

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 90.9 to 535.7 ...		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section.	054771

(3) *Minor species*—

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8 .....	.....	1. Young sheep: For the prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i> , <i>E. crandallis</i> , <i>E. parva</i> , and <i>E. bakuensis</i> .	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for human consumption.	054771
.....	.....	2. Young goats: For the prevention of coccidiosis caused by <i>Eimeria christenseni</i> and <i>E. ninakohlyakimovae</i> .	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for human consumption.	.....
(ii) 90.9 to 535.7 ...	.....	1. Young sheep: For the prevention of coccidiosis caused by <i>Eimeria ovinoidalis</i> , <i>E. crandallis</i> , <i>E. parva</i> , and <i>E. bakuensis</i> .	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for human consumption.	054771
.....	.....	2. Young goats: For the prevention of coccidiosis caused by <i>Eimeria christenseni</i> and <i>E. ninakohlyakimovae</i> .	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for human consumption.	.....

\* \* \* \* \*

§§ 558.198 and 558.205 [Redesignated as §§ 558.205 and 558.198]

■ 21. Redesignate §§ 558.198 and 558.205 as §§ 558.205 and 558.198, respectively.

■ 22. Revise newly redesignated § 558.198 to read as follows:

§ 558.198 **Dichlorvos.**

(a) *Specifications.* Each pound of Type A medicated article containing 3.1 or 9.6 percent dichlorvos.

(b) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.180 of this chapter.

(d) *Special considerations*—(1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feeds to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Feed must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing this preparation or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in

animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. If human or animal poisoning should occur, immediately consult a physician or a veterinarian. Atropine is antidotal.

(3) Labeling for Type A articles and Type B feeds must include a statement that containers or materials used in packaging such Type A articles and Type B feeds are not to be reused and all such packaging materials must be destroyed after the product has been used.

(e) *Conditions of use.* It is used in swine feed as follows:

Dichlorvos grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 348 .....		Swine up to 70 pounds body weight: For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm ( <i>Trichuris suis</i> ), nodular worm ( <i>Oesophagostomum</i> sp.), large roundworm ( <i>Ascaris suum</i> ) and the thick stomach worm ( <i>Ascarops strongylina</i> ) of the gastrointestinal tract.	Feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the medicated feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.	054628

Dichlorvos grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 479 .....		Boars, open or bred gilts, and sows: For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm ( <i>Trichuris suis</i> ), nodular worm ( <i>Oesophagostomum</i> sp.), large roundworm ( <i>Ascaris suum</i> ) and the thick stomach worm ( <i>Ascarops strongylina</i> ) of the gastrointestinal tract.	Feed as sole ration at the rate of 6 pounds per head for one feeding.	054628
(iii) 334 to 500 .....		Pregnant swine: An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth stage larvae of whipworm ( <i>Trichuris suis</i> ), nodular worm ( <i>Oesophagostomum</i> spp.) large roundworm ( <i>Ascaris suum</i> ), and the thick stomach worm ( <i>Ascarops strongylina</i> ) occurring in the gastrointestinal tract of the sow or gilt.	Mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.	054628

■ 23. In newly redesignated § 558.205, revise paragraphs (b) and (d)(1) and (2) to read as follows:

**§ 558.205 Diclazuril.**

\* \* \* \* \*

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

\* \* \* \* \*

(d) \* \* \*

(1) *Chickens.* For chickens it is used as follows:

Diclazuril grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 .....		Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> .	Feed continuously. Not for use in hens producing eggs for human food. Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> .	058198
(ii) 0.91 .....	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously. Not for use in hens producing eggs for human food. Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> . Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91 .....	Bambermycins, 1 to 2 ...	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis (mivati)</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously. Not for use in hens producing eggs for human food. Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> . Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

(2) *Turkeys.* For turkeys it is used as follows:

Diclazuril grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 .....		Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. gallopavonis</i> and <i>E. meleagrimitis</i> .	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption.	058198
(ii) 0.91 .....	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. gallopavonis</i> and <i>E. meleagrimitis</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 0.91 .....	Bambermycins, 1 to 2 ...	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. gallopavonis</i> and <i>E. meleagrimitis</i> , and for improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

Diclazuril grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iv) 0.91 .....	Bambermycins, 2 .....	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoides</i> , <i>E. gallopavonis</i> and <i>E. meleagridis</i> , and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

\* \* \* \* \*

■ 24. In § 558.258, revise paragraph (e)(2) to read as follows:

**§ 558.258 Fenbendazole.**

\* \* \* \* \*

(e) \* \* \*

(2) *Swine.*

Fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsors
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period..		For the removal and control of adult stage lungworms ( <i>Metastrongylus apri</i> and <i>M. pudendotectus</i> ); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms ( <i>Ascaris suum</i> ); adult stage nodular worms ( <i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i> ); adult stage small stomach worms ( <i>Hyostrogylus rubidus</i> ); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms ( <i>Trichuris suis</i> ); adult and larvae kidney worms ( <i>Stephanurus dentatus</i> ).	Feed as the sole ration	000061
(ii) 10 to 300 (to provide 9 mg/kg of body weight)..	Bacitracin methylenedisalicylate, 10 to 30.	Growing/finishing swine: For the removal and control of adult stage lungworms ( <i>Metastrongylus apri</i> and <i>M. pudendotectus</i> ); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms ( <i>Ascaris suum</i> ); adult stage nodular worms ( <i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i> ); adult stage small stomach worms ( <i>Hyostrogylus rubidus</i> ); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms ( <i>Trichuris suis</i> ); adult and larvae kidney worms ( <i>Stephanurus dentatus</i> ); and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter	054771
(iii) 10 to 300 (to provide 9 mg/kg of body weight)..	Bacitracin methylenedisalicylate, 250.	1. Growing/finishing swine: For the removal and control of adult stage lungworms ( <i>Metastrongylus apri</i> and <i>M. pudendotectus</i> ); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms ( <i>Ascaris suum</i> ); adult stage nodular worms ( <i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i> ); adult stage small stomach worms ( <i>Hyostrogylus rubidus</i> ); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms ( <i>Trichuris suis</i> ); adult and larvae kidney worms ( <i>Stephanurus dentatus</i> ); and for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition. 2. Pregnant sows: For the removal and control of adult stage lungworms ( <i>Metastrongylus apri</i> and <i>M. pudendotectus</i> ); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms ( <i>Ascaris suum</i> ); adult stage nodular worms ( <i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i> ); adult stage small stomach worms ( <i>Hyostrogylus rubidus</i> ); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms ( <i>Trichuris suis</i> ); adult and larvae kidney worms ( <i>Stephanurus dentatus</i> ); for control of clostridial enteritis in suckling pigs caused by <i>Clostridium perfringens</i> .	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter  2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771

\* \* \* \* \*

■ 25. In § 558.300, revise paragraph (e) to read as follows:

**§ 558.300 Ivermectin.**

\* \* \* \* \*

(e) *Conditions of use in swine.* It is used in feed as follows:

Ivermectin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 1.8 .....		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms ( <i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrongylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms ( <i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms ( <i>Metastrongylus</i> spp., adults); threadworms ( <i>Strongyloides ransomi</i> , adults and somatic larvae); lice ( <i>Haematopinus suis</i> ); and mange mites ( <i>Sarcoptes scabiei</i> var. <i>suis</i> ).	Feed as the only feed for 7 consecutive days to provide 0.1 milligrams per kilograms (mg/kg) of body weight per day. Withdraw 5 days before slaughter.	050604
(2) 1.8 .....	Bacitracin methylenedisalicylate, 10 to 30.	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms ( <i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrongylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms ( <i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms ( <i>Metastrongylus</i> spp., adults); threadworms ( <i>Strongyloides ransomi</i> , adults and somatic larvae); lice ( <i>Haematopinus suis</i> ); and mange mites ( <i>Sarcoptes scabiei</i> var. <i>suis</i> ); and for increased rate of weight gain and improved feed efficiency.	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604
(3) 1.8 .....	Bacitracin methylenedisalicylate, 250.	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms ( <i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrongylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms ( <i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms ( <i>Metastrongylus</i> spp., adults); threadworms ( <i>Strongyloides ransomi</i> , adults and somatic larvae); lice ( <i>Haematopinus suis</i> ); and mange mites ( <i>Sarcoptes scabiei</i> var. <i>suis</i> ); and for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604
(4) 1.8 to 11.8 .....		Adult and breeding swine: For treatment and control of gastrointestinal roundworms ( <i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrongylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms ( <i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms ( <i>Metastrongylus</i> spp., adults); threadworms ( <i>Strongyloides ransomi</i> , adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice ( <i>Haematopinus suis</i> ); and mange mites ( <i>Sarcoptes scabiei</i> var. <i>suis</i> ).	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604
(5) 1.8 to 11.8 .....	Bacitracin methylenedisalicylate, 250.	Pregnant sows: For treatment and control of gastrointestinal roundworms ( <i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrongylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms ( <i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms ( <i>Metastrongylus</i> spp., adults); threadworms ( <i>Strongyloides ransomi</i> , adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice ( <i>Haematopinus suis</i> ); and mange mites ( <i>Sarcoptes scabiei</i> var. <i>suis</i> ); and for control of clostridial enteritis caused by <i>Clostridium perfringens</i> in suckling piglets.	Feed as the only feed for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter. Feed bacitracin methylenedisalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604

Ivermectin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(6) 18.2 to 120 .....		Adult and breeding swine: For treatment and control of gastrointestinal roundworms ( <i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostromylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms ( <i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms ( <i>Metastrongylus</i> spp., adults); threadworms ( <i>Strongyloides ransomi</i> , adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice ( <i>Haematopinus suis</i> ); and mange mites ( <i>Sarcoptes scabiei</i> var. <i>suis</i> ).	Top dress on daily ration for individual treatment for 7 consecutive days to provide 0.1 mg/kg of body weight per day. Withdraw 5 days before slaughter.	050604

\* \* \* \* \*

**§ 558.325 Lincomycin.**

(1) \* \* \*

■ 26. In § 558.325, add paragraph (e)(1)(iii) to read as follows:

\* \* \* \* \*  
(e) \* \* \*

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(iii) 2 .....	Clopidol, 113.5 .....	Broiler chickens: For the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin, and as an aid in the prevention of cecal and intestinal coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	Feed as the sole ration to broiler chickens. Do not feed to chickens over 16 weeks of age. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Clopidol as provided by No. 016592 in § 510.600 of this chapter.	054771

\* \* \* \* \*

■ 27. Add § 558.330 to read as follows:

grams (10 grams per kilogram) of lubabegron as lubabegron fumarate.

(d) *Conditions of use.* It is used in cattle feed as follows:

**§ 558.330 Lubabegron.**

(a) *Specifications.* Each pound of Type A medicated article contains 4.54

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.  
(c) *Related tolerances.* See § 556.370 of this chapter.

Lubabegron grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(1) 1.25 to 4.54 .....		Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight during the last 14 to 91 days on feed.	Feed 1.25 to 4.54 g/ton (1.39 to 5 ppm) of complete feed (90% dry matter basis) to provide 13 to 90 milligrams lubabegron/head/day continuously. Do not allow horses or other equines access to feed containing lubabegron. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals.	058198
(ii) [Reserved]				

■ 28. In § 558.415, revise paragraph (d) to read as follows:

**§ 558.415 Novobiocin.**

(d) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens*—

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) To provide 6 to 7 milligrams per pound (mg/lb) of body weight per day.	Chickens: As an aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying chickens. Withdraw 4 days before slaughter.	054771
(ii) To provide 10 to 14 mg/lb of body weight per day.	Chickens: For the treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.	Administer feed which contains not less than 350 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying chickens. Withdraw 4 days before slaughter.	054771

(2) Turkeys—

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) To provide 4 to 5 mg/lb of body weight per day.	Turkeys: As an aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying turkeys. Withdraw 4 days before slaughter.	054771
(ii) To provide 5 to 8 mg/lb of body weight per day.	Turkeys: As an aid in the control of recurring outbreaks of fowl cholera caused by strains of <i>Pasteurella multocida</i> susceptible to novobiocin following initial treatment with 7 to 8 mg/lb of body weight per day.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying turkeys. Withdraw 4 days before slaughter.	054771
(iii) To provide 7 to 8 mg/lb of body weight per day.	Turkeys: For the treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin; and treatment of acute outbreaks of fowl cholera caused by strains of <i>Pasteurella multocida</i> susceptible to novobiocin.	Administer feed which contains not less than 350 grams of novobiocin activity per ton of feed as the sole ration for 5 to 7 days. Not for laying turkeys. Withdraw 4 days before slaughter.	054771

(3) Minor species—

Novobiocin amount	Indications for use	Limitations	Sponsor
(i) 350 grams per ton.	Ducks: For the control of infectious serositis and fowl cholera in ducks caused by <i>Pasteurella anatipestifer</i> and <i>P. multocida</i> , susceptible to novobiocin.	Administer as the sole ration for 5 to 7 days. Continue medication for 14 days if necessary. Repeat if reinfection occurs. Discontinue use at least 3 days before slaughter. Not for use in laying ducks.	054771
(ii) To provide 20 mg/lb of body weight per day.	Mink: For the treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.	Administer feed which contains not less than 200 grams of novobiocin activity per ton of feed as the sole ration for 7 days.	054771

■ 29. In § 558.450, redesignate paragraphs (e)(5)(iii), (iv), and (v) as paragraphs (e)(v), (iii), and (iv) respectively; and revise newly

redesignated paragraphs (e)(5)(iv) and (v) to read as follows:

§ 558.450 Oxytetracycline.

- \* \* \* \* \*
- (e) \* \* \*
- (5) \* \* \*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(iv) 3.75 g/100 lb of fish/day.	* * * 3. Freshwater-reared salmonids weighing up to 55 grams: For marking the skeletal tissue.	* * * Feed for 10 days. Immediate release is permitted following the last feeding of medicated feed.	066104
(v) 11.35 g/100 lb of fish/day.	* * * Pacific salmon not over 30 grams body weight: For marking of skeletal tissue.	* * * Administer medicated feed as the sole ration for 4 consecutive days. Do not liberate for at least 7 days following last feeding of medicated feed.	066104

\* \* \* \* \*

■ 30. In § 558.575, revise paragraphs (b) and (e) to read as follows:

§ 558.575 Sulfadimethoxine and ormetoprim.

\* \* \* \* \*

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 054771 for use of the product described in paragraph (a)(1) as in paragraphs (e)(1), (e)(2)(i), and (e)(3)(i) through (iii) of this section.

(2) No. 015331 for use of the product described in paragraph (a)(2) as in paragraphs (e)(3)(iv) and (v) of this section.

\* \* \* \* \*

(e) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens—*

Sulfadimethoxine and ormetoprim grams/ton	Indications for use	Limitations	Sponsors
(i) Sulfadimethoxine, 113.5; ormetoprim, 68.1.	Broiler chickens: As an aid in the prevention of coccidiosis caused by all <i>Eimeria</i> species known to be pathogenic to chickens, namely, <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and bacterial infections due to <i>Heterakis gallinarum</i> (infectious coryza), <i>Escherichia coli</i> (colibacillosis) and <i>Pasteurella multocida</i> (fowl cholera).	Feed as sole ration. Withdraw 5 days before slaughter.	054771
(ii) Sulfadimethoxine, 113.5; ormetoprim, 68.1.	Replacement chickens: As an aid in the prevention of coccidiosis caused by all <i>Eimeria</i> species known to be pathogenic to chickens, namely, <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and bacterial infections due to <i>Heterakis gallinarum</i> (infectious coryza), <i>Escherichia coli</i> (colibacillosis) and <i>Pasteurella multocida</i> (fowl cholera).	Feed as sole ration. Do not feed to chickens over 16 weeks (112 days) of age. Withdraw 5 days before slaughter.	054771

(2) Turkeys—

Sulfadimethoxine and ormetoprim grams/ton	Indications for use	Limitations	Sponsors
(i) Sulfadimethoxine, 56.75; ormetoprim, 34.05.	Turkeys: As an aid in the prevention of coccidiosis caused by all <i>Eimeria</i> species known to be pathogenic to turkeys, namely, <i>E. adenoides</i> , <i>E. gallopavonis</i> , and <i>E. meleagrimitis</i> and bacterial infection due to <i>Pasteurella multocida</i> (fowl cholera).	Do not feed to turkeys producing eggs for food. Withdraw 5 days before slaughter.	054771
(ii) [Reserved]			

(3) Minor species—

Sulfadimethoxine and ormetoprim amount	Indications for use	Limitations	Sponsors
(i) Sulfadimethoxine, 227; ormetoprim, 136.2 grams/ton of feed.	Ducks, including breeding ducks: As an aid in the control of bacterial infections due to <i>Pasteurella multocida</i> (fowl cholera).	Feed as sole ration for 7 days. Medication should be started at the first signs of infection. Do not feed to ducks producing eggs for food. Withdraw 5 days before slaughter.	054771
(ii) Sulfadimethoxine, 454; ormetoprim, 272.4 grams/ton of feed.	Ducks: As an aid in the control of bacterial infections due to <i>Escherichia coli</i> , <i>Riemerella anatipestifer</i> , and severe challenge of <i>Pasteurella multocida</i> (fowl cholera).	Feed as a sole ration for 7 days. Medication should be started at the first signs of infection. Not for breeding ducks. Do not feed to ducks producing eggs for food. Withdraw 5 days before slaughter.	054771
(iii) Sulfadimethoxine, 113.5; ormetoprim, 68.1 grams/ton of feed.	Chukar partridges: For prevention of coccidiosis caused by <i>Eimeria kofoidi</i> and <i>E. legionensis</i> .	Feed continuously to young birds up to 8 weeks of age as sole ration.	054771
(iv) 50 milligrams (mg) of active ingredients per kilogram of body weight per day.	Salmonids: For the control of furunculosis in salmonids (trout and salmon) caused by <i>Aeromonas salmonicida</i> strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 42 days before release as stocker fish or slaughter.	015331
(v) 50 mg of active ingredients per kilogram of body weight per day.	Catfish: For control of enteric septicemia of catfish caused by <i>Edwardsiella ictaluri</i> strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 3 days before slaughter or release as stocker fish.	015331

■ 30. Revise § 558.600 to read as follows:

**§ 558.600 Thiabendazole.**

(a) *Specifications.* Type A medicated articles containing 22, 44.1, 66.1, and 88.2 percent thiabendazole. The 66.1 percent Type A is solely for the

manufacture of cane molasses liquid Type B feed which is mixed in dry feeds. The 88.2 percent Type A is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Special considerations.* Do not use in Type B or Type C medicated feed containing bentonite.

(e) *Conditions of use.* It is used in medicated feed as follows:

(1) *Cattle—*

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) To provide 3 grams per 100 lb of body weight.	Cattle: For control of infections of gastrointestinal roundworms ( <i>Trichostrongylus</i> spp., <i>Haemonchus</i> spp., <i>Ostertagia</i> spp., <i>Nematodirus</i> spp., <i>Oesophagostomum radiatum</i> ).	Use 3 grams per 100 lb of body weight as a single dose. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604

Thiabendazole amount	Indications for use	Limitations	Sponsor
(ii) To provide 5 grams per 100 lb of body weight.	Cattle: For control of severe infections of gastrointestinal roundworms ( <i>Trichostrongylus</i> spp., <i>Haemonchus</i> spp., <i>Ostertagia</i> spp., <i>Nematodirus</i> spp., <i>Oesophagostomum radiatum</i> ); control of infections of <i>Cooperia</i> spp.	Administer 5 grams per 100 lb of body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604

(2) Swine—

Thiabendazole in grams/ton	Indications for use	Limitations	Sponsor
(i) 45.4 to 908	Swine: As an aid in the prevention of infections of large roundworms (genus <i>Ascaris</i> ).	Administer continuously feed containing 0.05 to 0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005 to 0.02 percent thiabendazole per ton for 8 to 14 weeks. Do not treat animals within 30 days of slaughter.	050604
(ii) [Reserved]			

(3) Minor species—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) To provide 2 grams per 100 lb of body weight.	Sheep and goats: For control of infections of gastrointestinal roundworms ( <i>Trichostrongylus</i> spp., <i>Haemonchus</i> spp., <i>Ostertagia</i> spp., <i>Cooperia</i> spp.; <i>Nematodirus</i> spp., <i>Bunostomum</i> spp., <i>Strongyloides</i> spp., <i>Chabertia</i> spp., and <i>Oesophagostomum</i> spp.); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of <i>T. colubriformis</i> and <i>axei</i> , <i>Ostertagia</i> spp., <i>Nematodirus</i> spp., <i>Strongyloides</i> spp.; less effective against those of <i>Haemonchus contortus</i> and <i>Oesophagostomum</i> spp.).	Use 2 grams per 100 lb of body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604
(ii) To provide 3 grams per 100 lb of body weight..	Goats: For control of severe infections of gastrointestinal roundworms ( <i>Trichostrongylus</i> spp., <i>Haemonchus</i> spp., <i>Ostertagia</i> spp., <i>Cooperia</i> spp., <i>Nematodirus</i> spp., <i>Bunostomum</i> spp., <i>Strongyloides</i> spp., <i>Chabertia</i> spp., and <i>Oesophagostomum</i> spp.).	Administer 3 grams per 100 lb of body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604
(iii) 454 grams/ton of feed .....	Pheasants: For the treatment of gapeworms ( <i>Syngamus trachea</i> ).	Feed continuously for 2 weeks (14 days). Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.	050604

■ 31. In § 558.633, revise paragraph (e) to read as follows:

**§ 558.633 Tylvalosin.**

(e) *Conditions of use.*

\* \* \* \* \*

Tylvalosin in grams/ton	Indications for use	Limitations	Sponsor
(i) 38.6 .....	Swine: For the control of porcine proliferative enteropathy (PPE) associated with <i>Lawsonia intracellularis</i> infection in groups of swine in buildings experiencing an outbreak of PPE.	Feed continuously as the sole ration for 14 consecutive days.	066916
(ii) [Reserved]			

Dated: March 26, 2019.

**Lowell J. Schiller,**

Acting Associate Commissioner for Policy.

[FR Doc. 2019-06136 Filed 4-1-19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 600**

[Docket No. FDA-2017-N-7007]

RIN 0910-AH49

**Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule amending the general biologics regulations relating to time of inspection requirements and also removing duties of inspector requirements. FDA is taking this action to remove outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug and device establishments, thereby providing flexibility without diminishing public health protections. This action is part of FDA's implementation of Executive Orders (E.O.s) 13771 and 13777. Under these E.O.s, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

**DATES:** This rule is effective May 2, 2019.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule 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:** Jenifer Stach, 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.

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**I. Executive Summary***A. Purpose of the Final Rule*

FDA is issuing this final rule to amend the general biologics regulations relating to time of inspection requirements and to remove duties of inspector requirements. FDA is taking this action to remove outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug and device establishments, thereby providing flexibility without diminishing public health protections.

*B. Summary of the Major Provisions of the Final Rule*

This final rule revises the time of inspection requirements contained in § 600.21 (21 CFR 600.21) and also removes the duties of inspector requirements contained in § 600.22 (21 CFR 600.22). These changes to the biological product regulations eliminate outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug and device establishments, thereby providing flexibility without diminishing public health protections. Revision and removal of these regulations does not change the biological product establishment inspection requirements and duties of an investigator requirements that apply under sections 704 and 510(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374 and 360(h)) and section 351(c) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(c)).

*C. Legal Authority*

FDA is taking this action under the biological product provisions of the PHS Act, and the drugs and general administrative provisions of the FD&C

Act, including sections 704 and 510(h) of the FD&C Act and section 351(c) of the PHS Act.

*D. Costs and Benefits*

Because this final rule does not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

**II. Background***A. Need for This Rulemaking*

In the **Federal Register** on January 26, 2018, FDA published a proposed rule entitled "Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products; Companion to Direct Final Rule" (83 FR 3631), as well as a companion direct final rule entitled "Removal of Certain Time of Inspection and Duties of Inspector Regulations for Biological Products" (83 FR 3586). To allow for consideration of the issues raised in the comments to the proposed rule, FDA withdrew the direct final rule in the **Federal Register** of May 7, 2018 (83 FR 19936). After careful consideration of these issues, FDA is issuing this final rule to revise the time of inspection requirements contained in § 600.21 and to remove the duties of inspector requirements contained in § 600.22. As discussed in the proposed rule, on February 24, 2017, President Donald Trump issued E.O. 13777, "Enforcing the Regulatory Reform Agenda" (82 FR 12285, March 1, 2017). One of the provisions in the E.O. requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As one step in implementing the E.O., FDA published a notice in the **Federal Register** of September 8, 2017 (82 FR 42492) entitled "Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirements." In that notice, FDA announced that it was conducting a review of existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of, and support, advances in innovation that have occurred since those regulations took effect. As part of this initiative, FDA is updating outdated regulations as specified in this rule.

FDA's general biological products regulations in part 600 (21 CFR part 600) are intended to help ensure the safety, purity, and potency of biological products administered to humans. The revision and removal of certain general biological products regulations are designed to eliminate outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for drug and device establishments, and provide flexibility without diminishing public health protections. Specifically, this final rule revises § 600.21 and removes § 600.22.

#### *B. Summary of Comments to the Proposed Rule*

We received five comments on the proposed rule from individual submitters. We received comments both in support of the proposed rule and comments raising concerns over the proposed revisions to §§ 600.21 and 600.22. These comments are further summarized in section IV.

#### *C. General Overview of the Final Rule*

As discussed in the proposed rule (83 FR 3631 at 3633), FDA's authority to conduct establishment inspections is included in both the FD&C Act and the PHS Act. Specifically, section 704 of the FD&C Act and section 351(c) of the PHS Act authorize the Agency to inspect establishments that manufacture biological products. Following enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) on July 9, 2012, and as provided under the provisions in E.O. 13777, FDA is revising § 600.21 and removing § 600.22.

FDA is revising § 600.21 to remove the biennial inspection requirement for biological product establishments that are registered as drug establishments and for those that are registered as device establishments. Before FDASIA was signed into law, section 510(h) of the FD&C Act provided, among other things, that drug and device establishments registered with FDA must be inspected on a biennial basis. Section 510(h) of the FD&C Act applies to biological product establishments because all biological products are subject to regulation under the drug or device provisions of the FD&C Act (in addition to the biological product provisions of the PHS Act). Since 1983, FDA's biological product regulation at § 600.21 has also included a biennial inspection requirement, which was consistent with the pre-FDASIA biennial inspection requirement in section 510(h) of the FD&C Act.

With the enactment of FDASIA, however, the biennial inspection requirement for drug establishments in section 510(h) of the FD&C Act was replaced with a requirement that FDA inspect drug establishments in accordance with a risk-based schedule established by FDA. Additionally, the FDA Reauthorization Act of 2017 (FDARA) was signed into law on August 18, 2017, and substantively amended the FD&C Act to, among other things, revise section 510(h)(2) such that the biennial inspection schedule for device establishments was also replaced by a risk-based schedule. FDA has determined that the biennial inspection requirement in § 600.21 regarding the frequency of inspections is outdated and no longer consistent with the FD&C Act (e.g., the risk-based inspection schedule for drug and device establishments may result in scheduling inspections at intervals of greater or less than 2 years for certain biological product establishments).

FDA is also removing provisions in § 600.21 concerning inspectional notice and the timing of pre-licensure reinspections of biological product establishments, as these provisions are outdated and unnecessary. As discussed in the proposed rule (83 FR 3631 at 3634), inspectional notice is addressed in the Agency's practices for inspections in its Standard Operating Procedures and Policies and in the Investigations Operations Manual (IOM). With respect to the timing of a reinspection of a biological product establishment following the denial of a biologics license application, the general biologics licensing provision at 21 CFR 601.4, which was issued subsequent to § 600.21, sets forth the administrative procedures following the denial of a license; accordingly, the specific provision in § 600.21 regarding timing of a reinspection following denial of a license is unnecessary.

FDA has further decided that current § 600.22, which requires specific duties of an FDA inspector, is unnecessary because the requirements in § 600.22(a) through (h) are duplicative of statutory requirements that apply to biological product inspections under section 704 of the FD&C Act. Specifically, the inspection requirements in section 704 of the FD&C Act encompass all of the requirements outlined in § 600.22. Thus, we are removing § 600.22(a) through (h).

The removal of these regulations, however, does not change the establishment inspection requirements and duties of investigator requirements specified in sections 704 and 510(h) of the FD&C Act, section 351(c) of the PHS

Act, or the procedures described in the IOM. Additionally, it does not change the established process for risk-based inspection planning and work planning.

### **III. Legal Authority**

FDA is issuing this rule under the biological products provisions of the PHS Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the FD&C Act (21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, and 379k–l). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and to prevent the introduction, transmission, and spread of communicable disease.

### **IV. Comments on the Proposed Rule and FDA Response**

#### *A. Introduction*

We received five comments on the proposed rule from individual submitters. We describe and respond to the comments in sections IV. B through IV. C. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance, or the order in which comments were received.

#### *B. Description of Comments Regarding Revisions to §§ 600.21 and 600.22*

(Comment 1) One comment supported the proposed rule.

(Response 1) We acknowledge and appreciate the supportive comment.

(Comment 2) One comment expressed concern that the risk-based inspection frequency will not be without negative health consequences. The comment also stated that “[R]isk Management is an identified known weak element to a majority of biological and medical device companies” and that the management and mitigation of risk without FDA oversight for a number of years is going to be a high-risk endeavor.

(Response 2) We disagree that the risk-based inspection frequency will have negative health consequences. The purpose of this rule is to remove outdated requirements and accommodate new approaches, such as a risk-based inspection frequency for

device and drug establishments. We believe this final rule will provide flexibility without diminishing public health protections. Furthermore, as discussed in the preamble to the proposed rule (83 FR 3633), establishing a risk-based schedule for inspections of drug establishments registered with FDA was mandated with the enactment of the FDASIA that was signed into law on July 9, 2012. In August 2017, FDARA mandated a risk-based schedule for inspections of device establishments registered with FDA. As a result of these amendments to the FD&C Act, sections 510(h)(2) and (3) of the FD&C Act now include requirements to establish a risk-based schedule for the inspection of drug and device establishments. In accordance with section 510(h)(4) of the FD&C Act, the risk-based schedule must consider, among other things, the known safety risks of such establishments, including the compliance history of the establishment; the record, history, and nature of recalls linked to the establishment; the inherent risk of the drug or device manufactured, prepared, propagated, compounded, or processed at the establishment; the inspection frequency and history of the establishment; and any other criteria deemed necessary and appropriate by FDA. While we agree that application of the risk-based inspection frequency may result in some establishments being inspected less frequently than every 2 years, these establishments will have been determined to be at a lower risk based on the Agency's evaluation of the above factors. In addition, the resources saved by performing less frequent inspections at lower risk establishments will allow FDA to inspect those establishments deemed higher risk more frequently if needed. Therefore, we believe the comment's concerns about negative health consequences are addressed during FDA's review of the known safety risks of drug and device establishments. The known safety risks that FDA must consider in establishing a risk-based schedule are outlined in section 510(h)(4) of the FD&C Act. With regard to "[R]isk Management," we note that any such discussion is outside the scope of this rule.

(Comment 3) One comment expressed concern with FDA's implementation and process for the review of existing regulations under E.O. 13771.

(Response 3) We reiterate that the purpose of this rule is to remove outdated requirements and accommodate new approaches, such as the risk-based inspection frequency for drug and device establishments required by the FD&C Act, and to provide flexibility without diminishing public

health protections. With regard to FDA's implementation and process for the review of existing regulations under E.O. 13771, we note that any such discussion is outside the scope of this rule.

(Comment 4) One comment expressed concern with respect to determining the frequency of inspections and asserted that any revised risk-based inspection schedule should provide for "both more relaxed and more frequent forms of inspection, if indicated by the conditions and risks that are assessed." The comment also asserted that FDA must "recognize that for products or processes for which quality is important and significant failures of quality are unacceptable, there may be a need for inspection more frequently than every two years, and with the degree of inspection and discussion now contained in the inspector duties under 600.20."

(Response 4) As discussed in the preamble to the proposed rule (83 FR 3633), the risk-based inspection schedule for drug and device establishments *may* result in scheduling inspections at intervals of greater than 2 years for *certain* biological product establishments. However, those establishments will have been determined to be at a lower risk based on evaluation of the factors included in section 510(h)(4) of the FD&C Act. In addition, the resources saved by performing less frequent inspections at lower risk establishments will allow FDA to inspect those establishments deemed higher risk more frequently when needed. We reiterate that the removal of these regulations will not change the establishment inspection requirements and duties of an investigator requirements specified in sections 704 and 510(h) of the FD&C Act and section 351(c) of the PHS Act. Additionally, it will not change the established process for risk-based inspection planning and work planning. Furthermore, this revision will not change FDA's authority to inspect an establishment for special cause, such as when FDA becomes aware of consumer complaints or adverse event reports, signaling a possible product quality issue for which a prompt inspection may be useful in investigating the matter. Therefore, while we agree, in part, with the comment, we believe the concerns expressed in the comment are addressed through FDA's review of the known safety risks of drug and device establishments and by FDA's ability to inspect as needed in the interest of patient safety. The known safety risks that FDA must consider in establishing

a risk-based schedule are outlined in section 510(h)(4) of the FD&C Act.

### C. Description of Comments Outside the Scope of This Rulemaking

(Comment 5) One comment requested an exemption to newly created Occupational Safety and Health Administration (OSHA) requirements.

(Response 5) We decline to respond because the request is outside the scope of this rule.

### V. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O. 12866 and E.O. 13563 direct us 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). E.O. 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule does not impose any additional regulatory burdens, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule is being issued to amend the general biologics regulations by removing certain time of inspection requirements and the duties of inspector requirements. This action is being taken

to remove outdated requirements, accommodate new approaches, and provide flexibility without diminishing public health protections. Because this rulemaking would remove regulations to be consistent with updated practice and does not impose any additional regulatory burdens, this rulemaking is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

#### VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) 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.

#### VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

#### IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

#### List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

#### PART 600—BIOLOGICAL PRODUCTS: GENERAL

- 1. The authority citation for part 600 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–l; 42 U.S.C. 216, 262, 263, 263a, 264.

#### § 600.21 [Amended]

- 2. Amend § 600.21 by removing the last three sentences.

#### § 600.22 [Removed and Reserved]

- 3. Remove and reserve § 600.22.

Dated: March 25, 2019.

**Scott Gottlieb,**

*Commissioner of Food and Drugs.*

[FR Doc. 2019–06187 Filed 4–1–19; 8:45 am]

**BILLING CODE 4164–01–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA–R03–OAR–2018–0153; FRL–9990–86–Region 3]

#### Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendment To Control of Emissions of Volatile Organic Compounds From Consumer Products

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving a revision to the State of Maryland's state implementation plan (SIP). The State of Maryland's SIP revision pertains to Code of Maryland Regulations (COMAR) 26.11.32—Control of Emissions of Volatile Organic Compounds (VOCs) from Consumer Products. This action is being taken under the Clean Air Act (CAA).

**DATES:** This final rule is effective on May 2, 2019.

**ADDRESSES:** EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2018–0153. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose

disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form.

Publicly available docket materials are available through [www.regulations.gov](http://www.regulations.gov), or please contact the person identified in the For FURTHER INFORMATION CONTACT section for additional availability information.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gregory Becoat, Office of Air Program Planning (3AP30), Air Protection Division, U.S. Environmental Protection Agency, Region 3, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2036. Mr. Becoat can also be reached via electronic mail at [becoat.gregory@epa.gov](mailto:becoat.gregory@epa.gov).

**SUPPLEMENTARY INFORMATION:** On November 16, 2017, the Maryland Department of Environment (MDE) submitted a revision to its SIP for COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products. The amendment is part of Maryland's strategy to achieve and maintain the 8-hour ozone national ambient air quality standards (NAAQS) throughout the State.

#### I. Background

EPA has designated certain areas within Maryland as nonattainment for the 2008 ozone NAAQS. See 40 CFR 81.321. Also, all of Maryland is included in the Ozone Transport Region (OTR) and is therefore treated as a moderate nonattainment area for ozone. See CAA section 184(a), (b)(2), 42 U.S.C. 7511c(a), (b)(2). Therefore, Maryland must continue to enact regulations to gain further reductions of the emissions of VOCs, a class of compounds that are precursors to ground-level ozone. Ozone is formed in the atmosphere by photochemical reactions between VOCs and oxides of nitrogen (NO<sub>x</sub>) in the presence of sunlight. In order to reduce ozone concentrations, the CAA requires control of VOC and NO<sub>x</sub> emission sources to achieve VOC and/or NO<sub>x</sub> emission reductions in nonattainment areas.

In December 1999, EPA identified emission reduction shortfalls in several severe 1-hour ozone nonattainment areas, including those located in the OTR. The Ozone Transport Commission (OTC) developed model rules for a number of source categories. One of the model rules was to reduce VOC emissions from consumer products. The OTC model rules are based on existing rules developed by the California Air Resources Board (CARB). The OTC

Model Rule for Consumer Products was first issued in March 28, 2001, revised November 29, 2001, and April 23, 2002. Additional amendments followed in 2006, 2010, and 2014. Maryland adopted the 2001 OTC model rule for consumer products under COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, on August 18, 2003. EPA approved Maryland's adopted regulation COMAR 26.11.32 as part of the SIP on December 8, 2004 (69 FR 70895). Maryland adopted the amended 2006 OTC model rule for consumer products under COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, on June 8, 2007. EPA approved Maryland's amended regulation into the SIP on December 10, 2007 (72 FR 69621). Maryland again amended its consumer products regulation and on October 18, 2010 (75 FR 63717), EPA approved Maryland's SIP revision to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products.

## II. Summary of SIP Revision and EPA Analysis

On November 16, 2017, Maryland submitted a SIP revision to amend COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, in order to institute the requirements of the 2010 and 2014 OTC model rules for consumer products. The 2010 and 2014 model rules were developed as part of a regional effort to attain and maintain the 8-hour ozone NAAQS and reduce 8-hour ozone levels. The 2010 OTC model rule reflected changes made by the 2006 CARB rule. The 2014 OTC model rule reflected changes made by the 2009 CARB rule. The OTC model rules further enhance VOC standards for specific consumer products and introduces VOC standards for new products. Generally, the amendments to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products regulations, established or amended VOC content limits and standards for a variety of consumer product categories, including personal care products, household products, automotive cleaners, and adhesives, in order to be consistent with the CARB and OTC model rules. More detailed information on these provisions, as well as a detailed summary of EPA's review and rationale for approving these SIP revisions, can be found in the notice of proposed rulemaking (NPR) for this action which is available on line at

[www.regulations.gov](http://www.regulations.gov), Docket number EPA-R03-OAR-2018-0153.

After evaluating the SIP revision submittal, EPA concluded that the revisions made to COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products, meet the SIP revision requirements of the CAA. The revision will continue to help Maryland attain and maintain the eight-hour ozone standard for the 2008 NAAQS. On August 8, 2018 (83 FR 39009), EPA published a NPR for the State of Maryland SIP revision. EPA received two comments, one which was a relevant adverse comment on the NPR, noting that the CARB and the OTC model rules referenced in the NPR were not in the docket on [www.regulations.gov](http://www.regulations.gov). As a result, EPA placed the missing CARB and OTC model rules into the docket for this action on August 16, 2018, and then published a supplemental NPR on November 26, 2018 (83 FR 57704), reopening the comment period for this action for thirty days. EPA received two additional comments during the supplemental NPR comment period. All comments received during the initial public comment period and the supplemental NPR comment period are addressed in Section III. Response to Comments of this rulemaking action.

## III. Response to Comments

During the two comment periods, EPA received four anonymous comments on the proposed rulemaking action. One comment generally discussed air quality in China and India. EPA believes this comment is not germane to this rulemaking and therefore no further response is provided. Two comments were supportive of EPA's approval of the State of Maryland's SIP revision and noted the air quality benefits of approving the CARB and OTC model rules into Maryland's SIP. EPA thanks those commenters and agrees that this SIP revision will have air quality benefits in Maryland. The fourth comment, received during the first public comment period, pointed out that the CARB and OTC regulations were not in the docket for the rule, which EPA corrected by issuing the supplemental NPR and, also, raised the comment discussed below.

*Comment #1:* The anonymous commenter stated: "Are you or are you not proposing to approve the hair styling gel category? The "Proposed Action" section makes it sound like you are approving everything except the hair styling gel category."

*Response #1:* EPA is approving the "hair styling product—all other forms"

category—which includes "hair styling gel"—into the Maryland SIP. As noted in the NPR published on August 8, 2018 (83 FR 39009), the 2006 CARB rule eliminated the "hair styling gel" category and now considers gels to fall under "hair styling product—all other forms" category. Considering hair styling gels to be part of the "hair styling product—all other forms" category resulted in a reduction of the hair styling gels VOC limit from 6 to 2 percent VOC by weight. The 2014 OTC model rule did not address the 2006 CARB rule amendment for hair styling gels. However, MDE rectified this omission in the 2014 OTC model rules when amending COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products, by moving the "hair styling gel" category into the "hair styling product—all other forms" category. Placing hair styling gels into the "hair styling product—all other forms" category reduces the VOC content to 2 percent VOC by weight and makes the Maryland regulations consistent with the 2006 CARB rules.

## IV. Final Action

EPA is approving the State of Maryland's November 16, 2017 SIP revision submittal that adopts the VOC limits established in the 2010 and 2014 OTC model rules for consumer products.

## V. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Maryland rule discussed in section II of this preamble. EPA has made, and will continue to make, these materials generally available through <http://www.regulations.gov> and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully Federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.<sup>1</sup>

<sup>1</sup> 62 FR 27968 (May 22, 1997).

**VI. Statutory and Executive Order Reviews**

**A. General Requirements**

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

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because it is not a significant action under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

**B. Submission to Congress and the Comptroller General**

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

**C. Petitions for Judicial Review**

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 3, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the

finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action, which approves the State of Maryland's COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2)).

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: March 4, 2019.

**Cecil Rodrigues,**

*Acting Regional Administrator, Region III.*

40 CFR part 52 is amended as follows:

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

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

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

**Subpart V—Maryland**

■ 2. In § 52.1070, the table in paragraph (c) is amended by:

- a. Revising entries for "26.11.32.01", "26.11.32.02", "26.11.32.03", "26.11.32.04", and "26.11.32.05";
- b. Adding an entry in numerical order for "26.11.32.05-1"; and
- c. Revising entries for "26.11.32.06", "26.11.32.08", "26.11.32.12", "26.11.32.14", and "26.11.32.16".

The revisions and addition read as follows:

**§ 52.1070 Identification of plan.**

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

**EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP**

Code of Maryland Administrative Regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
*	*	*	*	*
<b>26.11.32 Control of Emissions of Volatile Organic Compounds From Consumer Products</b>				
26.11.32.01 .....	Applicability and Exemptions .....	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.

EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP—Continued

Code of Maryland Administrative Regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
26.11.32.02 .....	Incorporation by Reference .....	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
26.11.32.03 .....	Definitions .....	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised. Previous Approval dated 12/10/2007.
26.11.32.04 .....	Standards—General .....	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
26.11.32.05 .....	Standards—Requirements for Charcoal Lighter Materials.	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
26.11.32.05–1 ...	Requirements for Flammable and Extremely Flammable Multi-Purpose Solvent and Paint Thinner.	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	New Regulation.
26.11.32.06 .....	Standards—Requirements for Aerosol Adhesives.	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
* * *	* * *	* * *	* * *	* * *
26.11.32.08 .....	Requirements for Contact Adhesives, Electronic Cleaners, Footwear, or Leather Care Products, and General Purpose Cleaners.	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
* * *	* * *	* * *	* * *	* * *
26.11.32.12 .....	Innovative Products—Department Exemption.	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
* * *	* * *	* * *	* * *	* * *
26.11.32.14 .....	Reporting Requirements .....	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
* * *	* * *	* * *	* * *	* * *
26.11.32.16 .....	Test Methods .....	10/09/2017	4/2/2019, Insert <b>Federal Register</b> citation].	Revised.
* * *	* * *	* * *	* * *	* * *

\* \* \* \* \*  
 [FR Doc. 2019-04779 Filed 4-1-19; 8:45 am]  
 BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R02-OAR-2017-0094; FRL-9991-50-Region 2]

**Approval and Promulgation of Implementation Plans: New York Ozone Section 185**

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

**SUMMARY:** The Environmental Protection Agency is finalizing approval of the State of New York’s Low Emissions Vehicle program as an alternative program to fulfill the Clean Air Act section 185 requirement for the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT

nonattainment area for the revoked 1979 1-hour ozone National Ambient Air Quality Standard. Clean Air Act section 185 requires fees to be paid by major sources located in ozone nonattainment areas classified as Severe or Extreme that have failed to attain the National Ambient Air Quality Standard by the required attainment date. The State of New York’s Low Emissions Vehicle program is being approved as an alternate program because the reductions achieved by the program are at least equivalent to the reductions associated with the Clean Air Act section 185 fee program required for the New York portion of the NY-NJ-CT nonattainment area.

**DATES:** This rule is effective on May 2, 2019.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-R02-OAR-2017-0094. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) website. Although listed in the index, some information is not publicly available,

e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through [www.regulations.gov](http://www.regulations.gov), or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

**FOR FURTHER INFORMATION CONTACT:** Gavin Lau, Environmental Protection Agency, Air Programs Branch, 290 Broadway, 25th Floor, New York, NY 10007-1866, (212) 637-3708, or by email at [Lau.Gavin@epa.gov](mailto:Lau.Gavin@epa.gov).

- SUPPLEMENTARY INFORMATION:**
- I. What action is the EPA taking?
  - II. What comments were received in response to the EPA’s proposed action?
  - III. What is the EPA’s conclusion?
  - IV. Statutory and Executive Order Reviews

### I. What action is the EPA taking?

The Environmental Protection Agency (EPA) is approving the State of New York's Low Emissions Vehicle (LEV II) program as an alternative program to fulfill the Clean Air Act (CAA) section 185 requirement for the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT nonattainment area for the revoked 1979 1-hour ozone National Ambient Air Quality Standard (NAAQS). The LEV II program will be incorporated into the federally enforceable SIP as an alternative CAA section 185 program. The reader is referred to the proposed rulemaking on this action published in the **Federal Register** (FR) on December 6, 2018 (83 FR 62771) for additional details.

### II. What comments were received in response to the EPA's proposed action?

The EPA received two comments in response to the EPA's December 6, 2018 proposed action. After reviewing the comments, the EPA has determined that the comments are generally in support of the EPA's proposed action. The comments also raise issues that are not germane to the EPA's proposed action and do not explain or provide a legal basis for how the proposed action should differ in any way. For this reason, the EPA will not provide a specific response to the comments and we are finalizing the action as proposed. The comments may be viewed under Docket ID Number EPA-R02-OAR-2017-0094 on the <http://www.regulations.gov> website.

### III. What is the EPA's conclusion?

The EPA has determined that New York's LEV II program is an approvable alternative program no less stringent than the program required by CAA section 185, consistent with the principles of CAA section 172(e). CAA section 172(e) provides that when the Administrator relaxes a NAAQS, the EPA must ensure that all areas which have not attained that NAAQS maintain "controls which are not less stringent than the controls applicable to areas designated nonattainment before such relaxation." CAA section 185 fee program requirements apply to ozone nonattainment areas classified as Severe or Extreme that fail to attain by the required attainment date. The requirements of CAA section 185 were applicable to the NY-NJ-CT nonattainment area for 2008 and 2009 since the area failed to attain the 1-hour ozone NAAQS by its attainment date. The NY-NJ-CT area later was determined to attain the 1-hour ozone

NAAQS for 2008–2010 (77 FR 36163). Consistent with the principles of CAA section 172(e), a state can meet the 1-hour ozone section 185 obligation through either the fee program prescribed in section 185 of the CAA or an equivalent alternative program, if the state demonstrates that the alternative is not less stringent than the otherwise applicable section 185 fee program. The EPA has determined that the New York State Department of Environmental Conservation, on behalf of the State of New York, demonstrated that New York's LEV II program provided emission reductions no less stringent than a CAA section 185 fee program for 2008 and 2009 and that it is an approvable equivalent alternative program to fulfill the Clean Air Act section 185 requirement for the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT nonattainment area for the revoked 1979 1-hour ozone NAAQS. New York's LEV II emission standards continue to be in place and achieve reductions in VOC and NO<sub>x</sub> emissions.

### IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 3, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed

and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Volatile organic compounds.

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

Dated: March 18, 2019.  
**Peter D. Lopez,**  
*Regional Administrator, Region 2.*

Part 52 chapter I, title 40 of the Code of Federal Regulations is amended as follows:

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

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

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

**Subpart HH—New York**

■ 2. In § 52.1670, the table in paragraph (e) is amended by adding the entry “Section 185 fee program” at the end of the table to read as follows:

**§ 52.1670 Identification of plan.**

\* \* \* \* \*  
 (e) \* \* \*

**EPA-APPROVED NEW YORK NONREGULATORY AND QUASI-REGULATORY PROVISIONS**

Action/SIP element	Applicable geographic or nonattainment area	New York submittal date	EPA approval date	Explanation
* Section 185 fee program.	* State-wide ...	* 1/31/2014, supplemented on 4/7/2014, 10/13/2016, and 4/3/2018.	* 4/2/2019, [insert <b>Federal Register</b> citation].	* Approval of the Low Emissions Vehicle Program (LEV II) as an alternative section 185 fee program

■ 3. In § 52.1683, add paragraph (r) to read as follows:

**§ 52.1683 Control strategy: Ozone.**

\* \* \* \* \*

(r) New York’s Section 185 Equivalency Demonstration State Implementation Plan revision submittal on January 31, 2014, and supplemented on April 7, 2014, October 13, 2016, and April 3, 2018, for the use of the State of New York’s Low Emissions Vehicle (LEV II) program as an alternative program to fulfill the Clean Air Act section 185 requirement for the New York portion of the New York-Northern New Jersey-Long Island, NY-NJ-CT nonattainment area for the revoked 1979 1-hour ozone National Ambient Air Quality Standard is approved.

[FR Doc. 2019-06294 Filed 4-1-19; 8:45 a.m.]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2018-0058; FRL-9988-62]

**2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters; Tolerance Exemption**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a

tolerance for residues of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters; when used as an inert ingredient in a pesticide chemical formulation. Lamberti USA, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters on food or feed commodities.

**DATES:** This regulation is effective April 2, 2019. Objections and requests for hearings must be received on or before June 3, 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-2018-0058, 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: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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 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](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0058 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 June 3, 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-2018-0058, 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. Background and Statutory Findings

In the **Federal Register** of May 18, 2018 (83 FR 23247) (FRL-9976-87), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN-11111) filed by Lamberti

USA, Incorporated, P.O. Box 1000, Hungerford TX 77448. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters; CAS Reg. No. 2115702-24-2. That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any comments.

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

## III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an

exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). 2-Methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF<sub>3</sub>- or longer chain length as listed in 40 CFR 723.250(d)(6). Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

8. The polymer's number average MW of 10,000 is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below

MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters.

#### IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters is 10,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

#### V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

EPA has not found 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters to share a common mechanism of toxicity with any other substances, and 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-

propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

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

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

#### VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, C12-16 alkyl esters.

#### VIII. Other Considerations

##### *Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### IX. Conclusion

Accordingly, EPA finds that exempting residues of 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-

methyl-, C12-16 alkyl esters from the requirement of a tolerance will be safe.

#### X. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

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

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

does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

**XI. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: February 26, 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 § 180.960, add alphanumerically the polymer to the table to read as follows:

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

\* \* \* \* \*

Polymer	CAS No.
* * * * *	
2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulfonic acid monosodium salt polymer with 2-propenoic acid, 2-methyl-, alkyl esters, minimum number average molecular weight (in amu), 10,000 .....	C12-16 2115702–24–2
* * * * *	

[FR Doc. 2019–06383 Filed 4–1–19; 8:45 am]  
**BILLING CODE 6560–50–P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2017–0616; FRL–9987–14]

**Metrafenone; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of metrafenone in or on mushroom. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 2, 2019. Objections and requests for hearings must be received on or before June 3, 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–2017–0616, 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: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0616 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 June 3, 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-2017-0616, 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.

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

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 27, 2018 (83 FR 8408) (FRL-9972-17), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8624) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.624 be amended by establishing a tolerance for residues of the fungicide metrafenone, (3-bromo-6-methoxy-2-methylphenyl) (2,3,4-trimethoxy-6-methylphenyl)methanone, in or on mushroom at 0.5 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing the tolerance for residues of metrafenone at 0.50 ppm to be consistent with EPA rounding class practices. Additionally, the tolerance is established for the commodity "White button mushroom" to reflect the mushroom variety tested in the supporting crop field trial studies.

## 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 metrafenone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with metrafenone 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 liver is the primary target organ for metrafenone in mice, rabbits and rats. Effects on the liver were seen in multiple studies throughout the database, including subchronic rat studies, the rabbit developmental toxicity study, and chronic studies in mice and rats. Liver effects observed in subchronic studies included increased liver weights, periportal cytoplasmic vacuolation, increased cholesterol, and hepatocellular hypertrophy. Liver effects observed in chronic studies included those from the subchronic studies as well as increased serum gamma glutamyl transferase,

eosinophilic alterations, necrosis, polyploid hepatocytes, bile duct hyperplasia, liver masses, and hepatocellular adenomas. The additional effects in the chronic studies indicate a progression of toxicity with time. The effects on the liver are consistent with the results of the absorption, distribution, metabolism, and excretion (ADME) studies indicating that the highest tissue concentrations of metrafenone were found in the liver and gastrointestinal tract and that bile is the primary route of excretion.

Additionally, nephrotoxicity was observed following chronic exposure to metrafenone in mice and rats. The kidney effects observed in the chronic studies included subacute/chronic interstitial inflammation and chronic/progressive nephropathy, cysts, brown pigment in renal cells, increased urinary volume, and increased urinary protein.

In a 28-day dermal toxicity study in rats, there were no dermal or systemic effects observed up to the highest dose tested of 1,000 mg/kg/day, the limit dose. In a 28-day immunotoxicity study in female rats, no effect on the immune system was observed up to the highest dose tested of 1,000 mg/kg/day, the limit dose. This is consistent with the rest of the database where no effects on the immune system were observed in any study.

There was no evidence of qualitative or quantitative susceptibility in the developmental and reproduction toxicity studies. In the developmental rat study, no effects were observed in dams or fetuses up to the limit dose of 1,000 mg/kg/day. In the rabbit study, liver toxicity (increased liver weights, hypertrophy, and hepatocyte vacuolation) was observed in the dams but no developmental effects were observed up to the limit dose of 1,000 mg/kg/day.

In the rat reproduction toxicity study, there was no evidence of reproductive toxicity. Effects in the offspring (decreased pup weight) occurred at doses similar to those that cause toxicity in the parental animals (decreased body weight).

The required battery of mutagenicity studies was submitted, including bacterial reverse mutation assay, mammalian cell mutation (CHO cells), in vitro chromosome aberration (CHO cells), micronucleus assay and unscheduled DNA synthesis in mammalian cells in culture. There is no evidence that metrafenone is genotoxic.

In the mouse carcinogenicity study, liver tumors (increased incidence of hepatocellular adenomas and adenomas plus carcinomas) were observed in male

mice at the highest dose of 1,109 mg/kg/day. In the rat chronic/carcinogenicity study, there was an increased incidence in hepatocellular adenomas in females at the high dose of 1,419 mg/kg/day. However, the tumors in the rat females were not considered in the weight-of-evidence finding because they were associated with excessive toxicity to the females, leading to a reduction of the dose during the study. The registrant submitted mechanistic studies to support a mode of action (MOA) for the liver tumors, but the studies were conducted in rats. Although the MOA was considered plausible, the Agency concluded the data on rats could not be used to support a MOA finding in mice. The Agency concluded that quantification of cancer risk using a non-linear approach would adequately account for all chronic toxicity (including carcinogenicity) that could result from exposure to metrafenone. The use of the chronic point of departure is protective based on the following reasons:

- A treatment-related increase in benign liver tumors was seen only in male CD-1 mice at doses that were adequate to assess the carcinogenicity.
- The liver tumors were observed at doses significantly higher (44x) than those currently used for risk assessment.
- No treatment-related tumors were seen in female mice.
- No treatment-related tumors were seen in male rats and liver tumors in female rats were seen only at the Limit Dose which was excessively toxic to females; no tumors were seen at the next dose of 5,000 ppm, which was considered adequate to assess carcinogenicity.
- There is no mutagenicity concern for metrafenone.

Specific information on the studies received and the nature of the adverse effects caused by metrafenone 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 document "Metrafenone. Human Health Risk Assessment for the Section 3 Registration for Use on Mushrooms" at pages 26–36 in docket ID number EPA-HQ-OPP-2017-0616.

#### 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for metrafenone used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of October 22, 2014 (79 FR 63047) (FRL-9917-56).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metrafenone, EPA considered exposure under the petitioned-for tolerance as well as all existing metrafenone tolerances in 40 CFR 180.624. EPA assessed dietary exposures from metrafenone in food as follows:

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

No such effects were identified in the toxicological studies for metrafenone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWWEA; 2003–2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), tolerance-level residues (using a 2X metabolism adjustment factor), and EPA's 2018 default processing factors (with the exception of

chemical-specific processing factors where available).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that the use of the chronic point of departure is appropriate for assessing cancer risk to metrafenone. Therefore, a separate dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for metrafenone. Tolerance level residues (using a 2X metabolism adjustment factor), default processing factors (with the exception of chemical-specific processing factors where available), and 100 PCT were assumed for all food commodities.

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

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of metrafenone total toxic residues for chronic exposures are estimated to be 14.52 ppb for surface water and 12.3 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 14.52 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). Metrafenone 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.”

EPA has not found metrafenone to share a common mechanism of toxicity with any other substances, and metrafenone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that metrafenone 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-pesticide-chemicals-and-other>.

#### 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 evidence of qualitative or quantitative susceptibility in the developmental and reproduction toxicity studies. In the developmental rat study, no effects were observed in dams or fetuses up to the limit dose of 1,000 mg/kg/day. In the rabbit study, liver toxicity (increased liver weights, hypertrophy, and hepatocyte vacuolation) was observed in the dams but no developmental effects were observed up to the limit dose of 1,000 mg/kg/day. In the rat reproduction toxicity study, there was no evidence of reproductive toxicity. Effects in the offspring (decreased pup weight) occurred at doses similar to those which cause toxicity in the parental animals (decreased body weight).

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 metrafenone is complete.
- ii. There is no indication that metrafenone 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 metrafenone results in increased susceptibility in *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 dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues (using a 2X metabolism adjustment factor), and EPA’s 2017 default processing factors (with the exception of chemical-specific processing factors where available). EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to metrafenone in drinking water. These assessments will not underestimate the exposure and risks posed by metrafenone.

#### E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, metrafenone is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to metrafenone from food and water will utilize 16% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for metrafenone.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate

exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

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

4. *Aggregate cancer risk for U.S. population.* EPA considers the chronic aggregate risk assessment to be protective of any aggregate cancer risk.

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

## IV. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology ((Method FAMS 105–01)) is available to enforce the tolerance expression. Additionally, BASF has proposed the QuEChERS LC–MS/MS method as a new enforcement method for metrafenone.

The method for Method FAMS 105–01 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](mailto: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 established an MRL for metrafenone in or on mushrooms at 0.5 ppm. The Codex MRL is for “Mushrooms” defined as VF 0450 to include button mushroom, Rodman’s agaricus mushroom and Hime-Matsutake, edible fungi. This MRL matches the tolerance established for metrafenone in or on white button mushroom in the United States, with the exception of the number of significant digits.

**C. Response to Comments**

Two comments were received in response to the Notice of Filing associated with this action, requesting that the Agency deny approval of the product due to impacts on the environment. Because the Agency’s role is to assess the safety of the tolerance, these comments are outside the scope of this rulemaking.

**V. Conclusion**

Therefore, tolerances are established for residues of metrafenone, (3-bromo-6-methoxy-2-methylphenyl) (2,3,4-trimethoxy-6-methylphenyl) methanone, in or on white button mushroom at 0.50 ppm.

**VI. Statutory and Executive Order Reviews**

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), 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: March 15, 2019.

**Donna Davis,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

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

■ 2. In § 180.624, add alphabetically the entry “White button mushroom” to the table in paragraph (a) to read as follows:

**§ 180.624 Metrafenone; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	
White button mushroom .....	0.50
* * * * *	

\* \* \* \* \*  
[FR Doc. 2019-06334 Filed 4-1-19; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2017-0665; FRL-9987-27]

**Zoxamide; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of zoxamide in or on Pepper/Eggplant Subgroup 8-10B. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective April 2, 2019. Objections and requests for hearings must be received on or before June 3, 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-2017-0665, 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](mailto: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](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions

provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0665 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 June 3, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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### II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 27, 2018 (83 FR 8408) (FRL-9972-17), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8615) by Gowan Company, 370 South Main Street, P.O. Box 5569, Yuma, AZ 85364. The petition requested that 40 CFR 180.567 be amended by establishing tolerances for residues of the fungicide zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide) in or on Pepper/Eggplant Subgroup 8-10B at 1.0 parts per million (ppm). That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the

docket, <http://www.regulations.gov>. That notice of filing document relied on the tolerance level referred to in the referenced summary, which requested a tolerance level as 0.9 ppm; however, the full submitted petition requested a tolerance level of 1.0 ppm, which the Agency used for the tolerance level and its safety assessment. One comment was received on the notice of filing; EPA's response is discussed 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 zoxamide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with zoxamide 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 toxicity data of zoxamide indicate that the primary target organ is the liver. Following zoxamide exposures, liver and thyroid weights increased along with liver histopathological changes and

increases in alkaline phosphatase. Systemic toxicity was not seen in the 28-day rat dermal toxicity study up to the limit dose. There are no concerns for neurotoxicity, immunotoxicity, developmental toxicity, or reproductive toxicity. There was no evidence of increased susceptibility (qualitative or quantitative) for the offspring in the reproduction studies or for fetuses following in utero exposure in the developmental studies. Zoxamide is classified as “not likely to be carcinogenic to humans” based on results from carcinogenicity studies in rats and mice.

Specific information on the studies received and the nature of the adverse effects caused by zoxamide 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 document *Zoxamide. Human Health Aggregate Risk Assessment for the Proposed New Uses on Pepper/Eggplant Subgroup 8–10B* at page 19 in docket ID number EPA–HQ–OPP–2017–0665.

#### 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 zoxamide used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of 18 July 2014 (79 FR 41911) (FRL–9913–35).

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to zoxamide, EPA considered exposure under the petitioned-for tolerances as well as all existing zoxamide tolerances in 40 CFR 180.567. EPA assessed dietary exposures from zoxamide in food as follows:

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) database. As to residue levels in food, EPA assumed tolerance level residues, 100% crop treated (CT), and default processing factors for all established and proposed commodities.

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

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for zoxamide. Tolerance level residues and/or 100% CT were assumed for all food commodities.

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

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide

Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of zoxamide for chronic exposures are estimated to be 22.84 parts per billion (ppb) for surface water and 65.8 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 65.8 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). Zoxamide 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.”

EPA has not found zoxamide to share a common mechanism of toxicity with any other substances, and zoxamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that zoxamide 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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this

provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.*

There was no evidence for increased susceptibility following prenatal exposure in developmental toxicity studies in rats and rabbits. Additionally, there was no evidence for increased susceptibility following pre- or postnatal exposure in the reproduction and fertility effects study in rats.

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 zoxamide is complete.
- ii. There is no indication that zoxamide 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 zoxamide results in increased susceptibility in *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 dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to zoxamide in drinking water. These assessments will not underestimate the exposure and risks posed by zoxamide.

*E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was

selected. Therefore, zoxamide is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to zoxamide from food and water will utilize 6.4% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for zoxamide.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short- and intermediate-term adverse effect was identified; however, zoxamide is not registered for any use patterns that would result in short- and intermediate-term residential exposure. Because there is no short- and intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-term risks), no further assessment of short- and intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for zoxamide.

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

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

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (Gas chromatography with electron capture detection (GC/ECD) and GC with mass selective detection (GC/MSD)) 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](mailto: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 MRLs for zoxamide for Pepper/Eggplant Subgroup 8–10B.

*C. Response to Comments*

In response to the notice of filing for this action, the Agency received the following from an anonymous citizen: “DENY APPROVAL [sic] OF THIS PRODUCT. IT SHOULD NOT BE USED ANYWHERE ON EARTH. IT IS HIGHLY TOXIC TO FISH AND IT PERSISTS IN THE ENVIRONMENT FOR LONG PERIODS OF TIME. DENY APPROVAL.” The concerns raised in this comment are outside the scope of the human health safety assessment conducted for this tolerance action. Section 408 of the FFDCA authorizes EPA to establish tolerances that it determines to be safe and instructs EPA when making that determination to consider information related to human health, not the environment. See 21 U.S.C. 346a(b)(2)(A), (C), (D).

**V. Conclusion**

Therefore, tolerances are established for residues of zoxamide, zoxamide (3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide), in or on Pepper/Eggplant Subgroup 8–10B at 1.0 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); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or 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: March 15, 2019.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

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

■ 2. In § 180.567, add alphabetically the commodity "Pepper/Eggplant Subgroup 8–10B" to the table in paragraph (a)(1) to read as follows:

§ 180.567 Zoxamide; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * * * *	*
Pepper/Eggplant Subgroup 8–10B .....	1.0
* * * * *	*

[FR Doc. 2019–06333 Filed 4–1–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180517486–8999–02]

RIN 0648–XG930

Atlantic Highly Migratory Species; Commercial Aggregated Large Coastal Shark and Hammerhead Shark Management Groups Retention Limit Adjustment

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

ACTION: Temporary rule; inseason retention limit adjustment.

SUMMARY: NMFS is adjusting the commercial aggregated large coastal shark (LCS) and hammerhead shark management group retention limit for directed shark limited access permit holders in the Atlantic region from 25 LCS other than sandbar sharks per vessel per trip to 3 LCS other than sandbar sharks per vessel per trip. NMFS is taking this action after considering the regulatory criteria regarding inseason adjustments to trip limits. The retention limit will remain at 3 LCS other than sandbar sharks per vessel per trip in the Atlantic region through the rest of the 2019 fishing season, unless NMFS announces another adjustment to the retention limit or a fishery closure with a separate notification in the Federal Register. This retention limit adjustment will affect anyone with a directed shark limited access permit fishing for LCS in the Atlantic region.

DATES: This retention limit adjustment is effective at 11:30 p.m. local time April 1, 2019, through the end of the 2019 fishing season on December 31, 2019, or until NMFS announces via a notification in the Federal Register another adjustment to the retention limit or a fishery closure, if warranted.

FOR FURTHER INFORMATION CONTACT: Lauren Latchford or Karyl Brewster-Geisz 301–427–8503; fax 301–713–1917.

SUPPLEMENTARY INFORMATION: Atlantic shark fisheries are managed under the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), its amendments, and implementing regulations (50 CFR part 635) issued under authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 et seq.).

Under § 635.24(a)(8), NMFS may adjust the commercial retention limit in the shark fisheries during the fishing season. Before making any adjustment, NMFS must consider specified regulatory criteria and other relevant factors see § 635.24(a)(8)(i)–(vi). After considering these criteria as discussed below, we have concluded that reducing the retention limit of the Atlantic aggregated LCS and hammerhead management groups for directed shark limited access permit holders will slow the fishery catch rates to allow the fishery throughout the Atlantic region to remain open for the rest of the year. Since landings for hammerhead sharks have reached approximately 24 percent of the quota and are projected to reach 80 percent by July, NMFS is reducing the commercial Atlantic aggregated LCS and hammerhead shark retention limit from 25 to 3 LCS other than sandbar per vessel per trip.

NMFS analyzed whether to reduce the retention limit for LCS other than sandbar sharks, considering the inseason retention limit adjustment criteria listed in § 635.24(a)(8), which includes:

- The amount of remaining shark quota in the relevant area, region, or sub-region, to date, based on dealer reports.

Based on dealer reports, 6.54 mt dw or 24 percent of the 27.1 mt dw shark quota for the hammerhead shark management group has already been landed in the Atlantic region. This means that approximately 76 percent of the quota remains.

- The catch rates of the relevant shark species/complexes in the region or sub-region, to date, based on dealer reports.

Dealer reports indicate a high level of average daily landings. At this level, hammerhead sharks are being harvested too quickly to ensure fishing opportunities throughout the season. If the current trip limit is left unchanged, hammerhead sharks would likely be harvested at such a high rate that there would not be enough hammerhead shark quota remaining to keep the fishery open year-round, precluding equitable fishing opportunities for the entire Atlantic region.

- Estimated date of fishery closure based on when the landings are projected to reach 80 percent of the quota given the realized catch rates.

Once the landings reach, or are projected to reach 80 percent of the quota, NMFS would have to close the hammerhead shark management group as well as the linked aggregated LCS management group, as required by existing regulations. Current catch rates would likely result in reaching 80

percent by July. A closure would preclude fishing opportunities in the Atlantic region for the remainder of the year.

- Effects of the adjustment on accomplishing the objectives of the 2006 Consolidated HMS FMP and its amendments.

Reducing the retention limit for the aggregated LCS and hammerhead management groups from 25 to 3 LCS per trip would allow for fishing opportunities later in the year consistent with the FMP's objectives to ensure equitable fishing opportunities throughout the fishing season and to limit bycatch and discards.

- Variations in seasonal distribution, abundance, or migratory patterns of the relevant shark species based on scientific and fishery-based knowledge.

The directed shark fisheries in the Atlantic region exhibit a mixed species composition, with a high abundance of aggregated LCS caught in conjunction with hammerhead sharks. As a result, by slowing the harvest and reducing landings on a per-trip basis, both fisheries could remain open for the remainder of the year.

- Effects of catch rates in one part of a region or sub-region precluding vessels in another part of that region or sub-region from having a reasonable opportunity to harvest a portion of the relevant quota.

Given the remaining quota and current catch rates, NMFS has concluded that the fishery is harvesting the hammerhead shark quota too quickly to ensure equitable fishing opportunities throughout the Atlantic. If the current trip limit is left unchanged, hammerhead sharks would likely be harvested at such a high rate that there would not be enough hammerhead shark quota remaining to keep the fishery open year-round. NMFS previously told the regulated community in a **Federal Register** notification (83 FR 60777) that a goal of this year's shark fishery is to ensure year-round shark fishing opportunities, but if the harvest of hammerhead shark quota is not slowed, we estimate that the fishery would reach 80 percent by July. Closing the fishery so early would prevent fishermen from the Northern part of the Atlantic region from having a reasonable opportunity to harvest the aggregated LCS and hammerhead quota, because the aggregated LCS and hammerhead management groups generally have not migrated to that area until later in the year.

On November 27, 2018 (83 FR 60777), NMFS announced that the aggregated LCS and hammerhead shark management groups for the Atlantic

region would open on January 1 with a quota of 168.9 metric tons (mt) dressed weight (dw) (372,552 lb dw) and 27.1 mt dw (59,736 lb dw), respectively. In that final rule, NMFS also indicated that if it appeared that the aggregated LCS or hammerhead shark management group quota was being harvested too quickly to allow fishermen throughout the entire region an opportunity to fish, (e.g., if approximately 20 percent of the quota is caught at the beginning of the year), NMFS would consider reducing the commercial retention limit for LCS other than sandbar sharks. Dealer reports through March 22, 2019, indicate that 6.54 mt dw or 24 percent of the available quota for the hammerhead shark management group has been harvested. If the average landings rate for the hammerhead shark management group reflected in the dealer reports continues, landings could reach 80 percent of the quota by the beginning of July. Once the landings reach 80 percent of the quota, NMFS would close both the aggregated LCS and hammerhead management group because they are linked under the regulations (§ 635.28(b)(3)).

Accordingly, as of 11:30 p.m. local time April 1, 2019, NMFS is reducing the retention limit for the commercial aggregated LCS and hammerhead shark management groups in the Atlantic region for directed shark limited access permit holders from 25 LCS other than sandbar sharks per vessel per trip to 3 LCS other than sandbar sharks per vessel per trip. If the vessel is properly permitted to operate as a charter vessel or headboat for HMS and is engaged in a for-hire trip, in which case the recreational retention limits for sharks and "no sale" provisions apply (§ 635.22(a) and (c)), or if the vessel possesses a valid shark research permit under § 635.32 and a NMFS-approved observer is onboard, then they are exempted from the retention limit adjustment.

All other retention limits and shark fisheries in the Atlantic region remain unchanged. This retention limit will remain at 3 LCS other than sandbar sharks per vessel per trip until NMFS announces via notification in the **Federal Register** another adjustment to the retention limit or a fishery closure is warranted.

The boundary between the Gulf of Mexico region and the Atlantic region is defined at § 635.27(b)(1) as a line beginning on the East Coast of Florida at the mainland at 25°20.4' N lat, proceeding due east. Any water and land to the north and east of that boundary is considered, for the purposes of quota monitoring and

setting of quotas, to be within the Atlantic region.

#### Classification

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA (AA), finds there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. Providing prior notice and an opportunity for comment is impracticable because the catch and landings that need to be reduced are ongoing and must be reduced immediately to meet conservation and management objectives for the fishery. Continued fishing at those levels during the time that notice and comment takes place would result in the much of the quota being landed and could result in a very early closure of the fishery,

contrary to the objectives of the existing conservation and management measures in place for those species. These objectives include ensuring that fishing opportunities are equitable and that bycatch and discards are minimized. Allowing fishing to continue at the existing rates even for a limited time is contrary to these objectives and would thus be impracticable. It would also be contrary to the public interest because, if the quota continues to be caught at the current levels, the quota will not last throughout the remainder of the fishing season and a large number of fishermen would be denied the opportunity to land sharks from the quota. Furthermore, continued catch at the current rates, even for a limited period, could result in eventual quota overharvests, since it is still so early in the fishing year. The AA also finds good

cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(d)(3) for the same reasons. This action is required under § 635.28(b)(2) and is exempt from review under Executive Order 12866. NMFS has concluded that reducing the retention limit of the Atlantic aggregated LCS and hammerhead management groups for directed shark limited access permit holders will slow the fishery catch rates to allow the fishery throughout the Atlantic region to remain open for the rest of the year.

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

Dated: March 28, 2019.

**Alan D. Risenhoover,**

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

[FR Doc. 2019-06369 Filed 3-28-19; 4:15 pm]

**BILLING CODE 3510-22-P**

# Proposed Rules

Federal Register

Vol. 84, No. 63

Tuesday, April 2, 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 ENERGY

### 10 CFR Parts 430 and 431

[EERE-2017-BT-STD-0062]

RIN 1904-AD38

#### Energy Conservation Program for Appliance Standards: Proposed Procedures for Use in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment

**AGENCY:** Office of Energy Efficiency and Renewable Energy, Department of Energy.

**ACTION:** Notice of public meeting and webinar and extension of public comment period.

**SUMMARY:** On February 13, 2019, the U.S. Department of Energy (DOE) published in the **Federal Register** a notice of proposed rulemaking and request for comment regarding proposals to update and modernize the Department's current rulemaking methodology titled, "Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products" (Process Rule). This notice announces a second public meeting, to be held on April 11, 2019, and an extension of the public comment period for submitting comments in response to the Process Rule. The comment period is extended from April 15, 2019, to May 6, 2019.

**DATES:** *Comments:* The comment period for the notice of proposed rulemaking and request for comment published on February 13, 2019 (84 FR 3910) is extended. Written comments and information are requested and will be accepted on or before May 6, 2019.

*Meeting:* DOE will hold a public meeting on Thursday, April 11, 2019, from 9 a.m. to 4:30 p.m. The meeting will also be broadcast as a webinar.

**ADDRESSES:** The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E-089, 1000

Independence Avenue SW, Washington, DC 20585.

Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE-2018-BT-STD-0018, by any of the following methods:

1. *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

2. *Email:* [Process.Rule@ee.doe.gov](mailto:Process.Rule@ee.doe.gov). Include the docket number EERE-2017-BT-STD-0062 and/or RIN number 1904-AD38 in the subject line of the message.

3. *Postal Mail:* Sofie Miller, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, Washington, DC 20585, Room 6A-013. Telephone: (202) 287-1445. If possible, please submit all items on a compact disc ("CD"), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Sofie Miller, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586-5000. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted.

*Docket:* The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at <https://www.regulations.gov>. All documents in the docket are listed in the <https://www.regulations.gov> index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at <https://www.regulations.gov/docket?D=EERE-2017-BT-STD-0062>. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

#### FOR FURTHER INFORMATION CONTACT:

Sofie Miller, Senior Advisor, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000

Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586-5000. Email: [Process.Rule@ee.doe.gov](mailto:Process.Rule@ee.doe.gov).

Francine Pinto, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586-7432. Email: [Francine.Pinto@hq.doe.gov](mailto:Francine.Pinto@hq.doe.gov).

#### SUPPLEMENTARY INFORMATION:

On February 13, 2019, the U.S. Department of Energy (DOE) published in the **Federal Register** a notice of proposed rulemaking and request for comment regarding proposals to update and modernize the Department's current rulemaking methodology titled, "Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products" ("Process Rule"). 84 FR 3910. That document announced a public meeting held on March 21, 2019, and request for written comments and information by April 15, 2019.

The public meeting held on March 21, 2019, did not address all of the content included in the notice of proposed rulemaking. Accordingly, DOE has determined that a second public meeting and extension of the comment period is appropriate. This notice announces that DOE will hold a second public meeting on April 11, 2019, to continue discussion on the proposal and to obtain input on topics not covered at the first public meeting. This notice also announces an extension of the public comment period for submitting comments in response to the proposal. The comment period is extended from April 15, 2019, to May 6, 2019. See section V, "Public Participation," of the notice published on February 13, 2019, for additional information on participating in the public meeting and submitting comments. *Id.*

Signed in Washington, DC, on March 27, 2019.

**Daniel R. Simmons,**

*Assistant Secretary, Energy Efficiency and Renewable Energy.*

[FR Doc. 2019-06364 Filed 4-1-19; 8:45 am]

**BILLING CODE 6450-01-P**

**DEPARTMENT OF ENERGY****10 CFR Part 431****[EERE–2018–BT–STD–0003]****Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Public Meetings for the Variable Refrigerant Flow Multi-Split Air Conditioners and Heat Pumps Working Group To Negotiate a Notice of Proposed Rulemaking for Test Procedures and Energy Conservation Standards****AGENCY:** Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.**ACTION:** Notice of public meeting and webinar.**SUMMARY:** The U.S. Department of Energy (DOE or the Department) announces a public meeting for the variable refrigerant flow multi-split air conditioners and heat pumps (VRF multi-split systems) working group. The Federal Advisory Committee Act (FACA) requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.**DATES:** DOE will hold a public meeting on Wednesday, April 17, 2019 from 9:00 a.m. to 5:00 p.m. and on Thursday, April 18, 2019 from 9:00 a.m. to 5:00 p.m. in Washington, DC. The meeting will also be broadcast as a webinar.**ADDRESSES:** The public meeting will be held at the U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585. On the first day, the meeting will be held in Room 8E–089, and on the second day, the meeting will be held in Room 1E–245. Please see the Public Participation section of this notice for additional information on attending the public meeting, including webinar registration information, participant instructions, and information about the capabilities available to webinar participants.**FOR FURTHER INFORMATION CONTACT:** Mr. John Cymbalsky, U.S. Department of Energy, Office of Building Technologies (EE–5B), 950 L'Enfant Plaza SW, Washington, DC 20024. Telephone: (202) 287–1692. Email: [ASRAC@ee.doe.gov](mailto:ASRAC@ee.doe.gov).**SUPPLEMENTARY INFORMATION:** On January 10, 2018, the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC) met and passed the recommendation to form a VRF multi-split systems working group to meet and discuss and, if possible, reach a consensus on proposed Federal test procedures and standards for VRF multi-split systems. On April 11, 2018,

DOE published a notice of intent to establish a working group for VRF multi-split systems to negotiate a notice of proposed rulemaking for test procedures and energy conservation standards. The notice also solicited nominations for membership to the working group. 83 FR 15514. This notice announces the next round of meetings for this working group.

DOE will host a public meeting and webinar on the following dates:

- Wednesday, April 17, 2019 from 9:00 a.m. to 5:00 p.m. at the U.S. Department of Energy, Room 8E–089, 1000 Independence Ave. SW, Washington, DC 20585.
- Thursday, April 18, 2019 from 9:00 a.m. to 5:00 p.m. at the U.S. Department of Energy Room, Room 1E–245, 1000 Independence Ave. SW, Washington, DC 20585.

The purpose of the meeting will be to negotiate in an attempt to reach consensus on proposed Federal test procedures and energy conservation standards for VRF multi-split systems.

**Public Participation***Attendance at Public Meeting*The times, dates, and locations of the public meeting are listed in the **DATES** and **ADDRESSES** sections of this document. If you plan to attend the public meeting, please notify the ASRAC staff at [asrac@ee.doe.gov](mailto:asrac@ee.doe.gov).Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting or webinar, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: [Regina.Washington@ee.doe.gov](mailto:Regina.Washington@ee.doe.gov) so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building will be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the visitor's desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific States and U.S. territories. DHS maintains an updated website identifying the State and

territory driver's licenses that currently are acceptable for entry into DOE facilities at <https://www.dhs.gov/real-id-enforcement-brief>. A driver's license from a State or territory identified as not compliant by DHS will not be accepted for building entry and one of the alternate forms of ID listed below will be required. Acceptable alternate forms of Photo-ID include U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by States and territories as identified on the DHS website (Enhanced licenses issued by these States and territories are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government-issued Photo-ID card.In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: <https://energy.gov/eere/buildings/appliance-standards-and-rulemaking-federal-advisory-committee>. Participants are responsible for ensuring their systems are compatible with the webinar software.*Procedure for Submitting Prepared General Statements for Distribution*Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **FOR FURTHER INFORMATION CONTACT** section of this notice. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by postal mail. DOE prefers to receive requests and advance copies via email. Please include a telephone number to enable DOE staff to make a follow-up contact, if needed.*Conduct of Public Meeting*ASRAC's Designated Federal Officer will preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. A transcript of the public meeting will be included on DOE's website: <https://energy.gov/eere/buildings/appliance-standards-and->

*rulemaking-federal-advisory-committee.* In addition, any person may buy a copy of the transcript from the transcribing reporter. Public comment and statements will be allowed prior to the close of the meeting.

#### Docket

The docket is available for review at <https://www.regulations.gov/docket?D=EERE-2018-BT-STD-0003>, including **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the <https://www.regulations.gov> index. However, not all documents listed in the index may be publically available, such as information that is exempt from public disclosure.

Signed in Washington, DC, on March 26, 2019.

**Valri Lightner,**

*Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.*

[FR Doc. 2019-06363 Filed 4-1-19; 8:45 am]

**BILLING CODE 6450-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 21

[Docket No. FAA-2019-0197]

#### **Airworthiness Criteria: Glider Design Criteria for Alexander Schleicher GmbH & Co. Segelflugzeugbau Model ASK 21 B Glider**

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

**ACTION:** Notice of proposed design criteria.

**SUMMARY:** This notice announces the availability of and requests comments on the proposed design criteria for the Alexander Schleicher GmbH & Co. Segelflugzeugbau Model ASK 21 B glider. The administrator finds the proposed design criteria for the Model ASK 21 B acceptable. These final design criteria will be published in the **Federal Register**.

**DATES:** Comments must be received on or before May 2, 2019.

**ADDRESSES:** Send comments identified by docket number FAA-2019-0197 using any of the following methods:

□ *Federal eRegulations Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

□ *Mail:* Send comments to Docket Operations, M-30, U.S. Department of

Transportation (DOT), 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC, 20590-0001.

□ *Hand Delivery of Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

□ *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* The FAA will post all comments it receives, without change, to <http://www.regulations.gov>, including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477-19478), as well as at <http://DocketsInfo.dot.gov>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jim Rutherford, AIR-692, Federal Aviation Administration, Policy & Innovation Division, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, MO 64106, telephone (816) 329-4165, FAX (816) 329-4090.

#### **SUPPLEMENTARY INFORMATION:**

##### **Comments Invited**

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the design criteria, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will consider all comments received on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these airworthiness design criteria based on received comments.

#### **Background**

On August 16, 2018, Alexander Schleicher GmbH & Co. Segelflugzeugbau (Alexander Schleicher) applied for validation of a type certificate change to add the Model ASK 21 B glider in accordance with the "Technical Implementation Procedures for Airworthiness and Environmental Certification Between the FAA and the European Aviation Safety Agency (EASA)," Revision 6, dated September 22, 2017. This model is a modified version of the Model ASK 21 glider and will be documented on existing Type Certificate Number (No.) G47EU. The Model ASK 21 B is a two-seat, mid-wing glider constructed from glass-fiber reinforced plastic and features a 55.8 foot (17 meters) wingspan with airbrakes on the upper wing surface. The glider has a non-retractable landing gear with a nose wheel and shock-absorbed, braked main wheel and a T-type tailplane. The glider has a maximum weight of 1,323 pounds (600 kilograms).

EASA type certificated the Model ASK 21 B glider in the utility and aerobatic categories and issued Type Certificate No. EASA.A.221, dated August 9, 2018. The associated EASA Type Certificate Data Sheet (TCDS) No. EASA.A.221 defined the certification basis, which Alexander Schleicher submitted to the FAA for review and acceptance.

Glider type certification by the FAA as special class aircraft for which airworthiness standards have not yet been established by regulation. Under the provisions of 14 CFR 21.17(b), the airworthiness standards for special class aircraft are those found by the FAA to be appropriate and applicable to the specific type design. FAA Advisory Circular (AC) 21.17-2A<sup>1</sup> provides guidance on acceptable design criteria for the type certification of gliders and powered gliders in the United States. AC 21.17-2A allows applicants to utilize the Joint Aviation Requirements (JAR)-22<sup>2</sup>, other airworthiness criteria comparable to 14 CFR part 23, or a combination of both as the means for showing compliance for glider certification.

#### **Type Certification Basis**

The certification basis for the Model ASK 21 B will be the same as the certification basis for the Model ASK 21 as shown on TCDS No. G47EU, Revision

<sup>1</sup> Ref AC 21.17-2A, "Type Certification—Fixed-Wing Gliders (Sailplanes), Including Powered Gliders," dated February 10, 1993.

<sup>2</sup> Ref JAR-22, "Sailplanes and Powered Sailplanes."

1, except for areas affected by the change, which will use EASA Certification Specification (CS)-22<sup>3</sup> as shown in these proposed airworthiness criteria.

### The Proposed Design Criteria

Applicable Airworthiness Criteria under 14 CFR 21.17(b).

Based on the Special Class provisions of § 21.17(b), the following airworthiness requirements form the FAA certification basis for the Model ASK 21 B:

1. 14 CFR part 21, effective February 1, 1965, including amendments 21-1 through 21-53.
2. Lufttuechtigkeitsforderungen fuer Segelflugzeuge and Motorsegler (LFSM) Airworthiness Requirements for Sailplanes and Powered Sailplanes, dated October 23, 1975.
3. JAR-22, dated April 1, 1980, including amendment 1, dated May 18, 1981.
4. CS-22, amendment 2, dated March 5, 2009, for the following regulations: CS 22.147, 22.455, 22.477, 22.561 except (b)(2), 22.595, 22.597, 22.629, 22.677, 22.685, 22.689, 22.721, 22.771, 22.773, 22.777, 22.779, 22.780, 22.781, 22.785, 22.786, 22.787, 22.788, 22.807, and 22.831.
5. AC 21.23-1, section 5(e)(6), dated January 12, 1981.
6. Operations are limited to Day VFR and to flying in Instrument Meteorological Conditions (IMC) if the glider is equipped as required under 14 CFR 91.205. Night operation is prohibited.
7. FAA Type Certificate Application Date: August 16, 2018.
8. EASA Type Certificate No. EASA.A.221, Issue 05, dated August 9, 2018.

Issued in Kansas City, Missouri, on March 21, 2019.

#### Pat Mullen,

Manager, Small Airplane Standards Branch, Aircraft Certification Service.

[FR Doc. 2019-06395 Filed 4-1-19; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2018-0690; Product Identifier 2018-CE-022-AD]

RIN 2120-AA64

#### Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

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

**ACTION:** Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

**SUMMARY:** We are revising an earlier proposal for certain Gulfstream Aerospace Corporation (Gulfstream) Model G-IV and Model GIV-X airplanes. This action revises the notice of proposed rulemaking (NPRM) by proposing to require a later revision of the service information to update the life limits and inspection requirements in the airworthiness limitations section (ALS) of the aircraft maintenance manual (AMM). We are proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM, we are reopening the comment period to allow the public the chance to comment on these changes.

**DATES:** The comment period for the NPRM published in the **Federal Register** on August 2, 2018 (83 FR 37771), is reopened.

We must receive comments on this SNPRM by May 17, 2019.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this SNPRM, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402-2206; telephone:

800-810-4853; fax: 912-965-3520; email: [pubs@gulfstream.com](mailto:pubs@gulfstream.com); Internet: <http://www.gulfstream.com/product-support/technical-publications>. You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

#### Examining the AD Docket

You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating FAA-2018-0690; 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 SNPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is listed above. Comments will be available in the AD docket shortly after receipt.

#### FOR FURTHER INFORMATION CONTACT:

Ronald "Ron" Wissing, Airframe Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: 404-474-5552; fax: 404-474-5606; email: [ronald.wissing@faa.gov](mailto:ronald.wissing@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2018-0690; Product Identifier 2018-CE-022-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this SNPRM. We will consider all comments received by the closing date and may amend this SNPRM because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this SNPRM.

#### Discussion

We issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain serial-numbered Gulfstream Model G-IV and Model GIV-X airplanes. The NPRM published in the **Federal Register** on August 2, 2018 (83 FR 37771). The NPRM was prompted by a revision to the ALS of the AMM based on fatigue and damage tolerance (FTD) testing and updated

<sup>3</sup> Ref EASA CS-22, "Certification Specifications for Sailplanes and Powered Sailplanes," amendment 2, dated March 5, 2009.

analysis. The NPRM proposed to require revising the ALS in the AMM to incorporate new inspections and life limits contained in Gulfstream Document No. GIV-GER-0008, Summary of Changes to the GIV Series and GIV-X Series Airworthiness Limitations, Revision B, dated March 12, 2018.

**Actions Since the NPRM Was Issued**

Since we issued the NPRM, Gulfstream updated the life limits in the ALS and issued Gulfstream Document No. GIV-GER-0008, Summary of Changes to the GIV Series and GIV-X Series Airworthiness Limitations, Revision D, dated August 20, 2018. Revision D differs from Revision B in that the part number (P/N) for the rudder for Model GIV airplanes has been corrected to reflect P/N 1159CS30004, and new life limits for fuselage cockpit side post P/N 1159BM50025-5 and P/N 1159BM50025-6 have been added per Revision C. Since incorporating Revision D instead of Revision B would impose an additional burden over those in the NPRM, we are reopening the comment period to allow the public the chance to comment on these changes.

**Comments**

We gave the public the opportunity to comment on the NPRM. The following presents the comment received on the NPRM and the FAA’s response to the comment.

**Request To Withdraw the NPRM**

An anonymous commenter indicated that the NPRM is unnecessary. The commenter stated the proposed requirements have already been incorporated into the manufacturer’s inspection program through a revision to the AMM, Chapter 5. According to

the commenter, the original equipment manufacturer (OEM) publishes revisions to the AMM on a CDROM or electronically through the OEM’s website; therefore, it would not be possible for the mechanic responsible for signing off on the AD to physically revise Chapter 5 of the AMM as required by the NPRM. The commenter noted the FAA’s estimated cost of compliance and stated that the NPRM does not increase safety, but rather it increases paperwork. We infer that the commenter wanted the NPRM withdrawn.

We do not agree. In accordance with 14 CFR 39.5, the FAA issues an AD addressing a product when we find that: (a) An unsafe condition exists in the product; and (b) the condition is likely to exist or develop in other products of the same type design. We will issue an AD if a revision to the AMM ALS addresses an unsafe condition, *i.e.*, more restrictive inspection intervals, altered non-destructive test (NDT) inspection requirements, and reduced life limits.

While Gulfstream operators may incorporate revisions to the AMM into their maintenance program, not all operators are required to do so. In order for the new life limits in Gulfstream Document No. GIV-GER-0008, Summary of Changes to the GIV Series and GIV-X Series Airworthiness Limitations, Revision D, dated August 20, 2018, to become mandatory, and to correct the unsafe condition identified in the NPRM, the FAA must require the changes by AD action.

**Related Service Information Under 1 CFR Part 51**

We reviewed Gulfstream Document No. GIV-GER-0008, Summary of Changes to the GIV Series and GIV-X Series Airworthiness Limitations, Revision D, dated August 20, 2018. The

service information describes more restrictive inspection intervals or altered NDT inspection requirements and updated life limits that address fatigue cracking of the principal structural elements (PSEs). Revision D of this service information differs from previous revisions in that it corrects the P/N for the rudder for Model GIV airplanes to reflect rudder P/N 1159CS30004 and adds new life limits for fuselage cockpit side post P/N 1159BM50025-5 and P/N 1159BM50025-6. 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.

**FAA’s Determination**

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

**Proposed Requirements of This SNPRM**

This SNPRM would require revising the ALS of the AMM, Chapter 5 Life Limited Components and Chapter 6 PSE Inspections Intervals, to incorporate new inspections and life limits based on FTD testing and updated analysis.

**Costs of Compliance**

We estimate that this proposed AD affects 711 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise ALS and AMM .....	20 work-hour × \$85 per hour = \$1,700.	Not applicable .....	\$1,700	\$1,208,700

The extent of damage found during the proposed inspection may vary from airplane to airplane. We have no way of determining the number of airplanes that might need repairs or the cost of such repairs for each airplane.

**Authority for This Rulemaking**

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of

the FAA Administrator. “Subtitle VII: Aviation Programs” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, section 44701: “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations

for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This proposed 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 small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation Division.

### Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a “significant regulatory action” under Executive Order 12866,

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

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

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

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

**Gulfstream Aerospace Corporation:** Docket No. FAA–2018–0690; Product Identifier 2018–CE–022–AD.

#### (a) Comments Due Date

We must receive comments by May 17, 2019.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model G–IV airplanes, certificated in any category, serial numbers 1000 through 1535; and Model GIV–X airplanes, certificated in any category, serial numbers 4001 through 4363.

Note 1 to paragraph (c) of this AD: Model G–IV airplanes are also referred to by the marketing designations G300 and G400. Model GIV–X airplanes are also referred to by the marketing designations G350 and G450.

#### (d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 27, Flight Controls; 32, Landing Gear; 52, Doors; 53, Fuselage; 55, Stabilizers; 57, Wings; 71, Power Plant-General; and 78, Engine Exhaust.

#### (e) Unsafe Condition

This AD was prompted by a revision to the airworthiness limitations section (ALS) of the Model G–IV and Model GIV–X aircraft maintenance manuals based on fatigue and damage tolerance testing and updated analysis. We are issuing this AD to detect and correct fatigue cracking of principal structural elements (PSEs). This unsafe condition, if unaddressed, could result in reduced structural integrity of a PSE or critical component and lead to loss of control of the airplane.

#### (f) Compliance

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

#### (g) Airplane Maintenance Manual Revisions

Within 12 months after the effective date of this AD, revise the ALS of your maintenance or inspection program (*e.g.*, maintenance manual) to incorporate the airworthiness limitations specified in Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision D, dated August 20, 2018, as applicable to your model and serial number airplane.

#### (h) No Alternative Actions or Intervals

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

#### (i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of

the person identified in paragraph (j)(1) of this AD.

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

#### (j) Related Information

(1) For more information about this AD, contact Ronald “Ron” Wissing, Airframe Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: 404–474–5552; fax: 404–474–5606; email: [ronald.wissing@faa.gov](mailto:ronald.wissing@faa.gov).

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Savannah, Georgia 31402–2206; telephone: (800) 810–4853; fax 912–965–3520; email: [pubs@gulfstream.com](mailto:pubs@gulfstream.com); Internet: <http://www.gulfstream.com/product-support/technical-publications>. You may view this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on March 25, 2019.

**Melvin J. Johnson,**

*Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR–601*

[FR Doc. 2019–06275 Filed 4–1–19; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA–2019–0203; Product Identifier 2018–CE–052–AD]**

**RIN 2120–AA64**

### Airworthiness Directives; Diamond Aircraft Industries GmbH Airplanes

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

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

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Diamond Aircraft Industries GmbH Model DA 42 NG and Model DA 42 M–NG airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The unsafe condition in the MCAI is insufficient clearance of the gust lock mounts on the pilot side rudder pedals. We are issuing this proposed AD to require actions to

address the unsafe condition on these products.

**DATES:** We must receive comments on this proposed AD by May 17, 2019.

**ADDRESSES:** You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A-2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; email: [office@diamond-air.at](mailto:office@diamond-air.at); Internet: <http://www.diamondaircraft.com>. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

#### 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-2019-0203; 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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

#### FOR FURTHER INFORMATION CONTACT:

Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: [mike.kiesov@faa.gov](mailto:mike.kiesov@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No.

FAA-2019-0203; Product Identifier 2018-CE-052-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

#### Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2018-0214, dated October 4, 2018 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

During production check-out of two DA 42 NG aeroplanes, it was noticed that, with the adjustable rudder pedals in full forward position, the gust lock mounts slightly touched the canopy gas spring damper. The subsequent investigation found that this was due to an unfavourable combination of production tolerances on these two aeroplanes. [Diamond Aircraft Industries GmbH] DAI determined that other aeroplanes of the same build standard (configuration) may also be affected.

This condition, if not corrected, could lead to restricted rudder travel, possibly resulting in reduced control of the aeroplane.

Prompted by these findings, DAI published the [mandatory service bulletin] MSB, providing modification instructions to remove the gust lock mounts on the pilot (left-hand, LH) side rudder pedals to ensure sufficient clearance, regardless of production tolerances and rudder pedal position.

For the reason described above, this [EASA] AD requires implementation of a temporary revision (TR) to the applicable Airplane Flight Manual (AFM) and a modification, removing the pilot (LH) side rudder pedal gust lock mounts.

You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0203.

#### Related Service Information Under 1 CFR Part 51

We reviewed Diamond Aircraft Temporary Revision TR-MAM 42-1097 Gustlock on Co-Pilot Side only, Doc. #7.01.15-E, dated July 18, 2018 (TR-MAM 42-1097), which contains amended figures related to the gust lock belt. We also reviewed Diamond Aircraft Industries GmbH Work Instruction WI-MSB 42NG-077, dated

August 20, 2018, which contains procedures for removing the pilot (LH) side rudder pedal gust lock mounts and specifies inserting a copy of TR-MAM 42-1097 into the airplane flight manual (AFM). 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.

#### FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

#### Costs of Compliance

We estimate that this proposed AD would affect 53 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the removal of the pilot side rudder pedal gust lock mounts and to insert copy of TR-MAM 42-1097 into the AFM. The average labor rate is \$85 per work-hour. Required parts would cost about \$10 per product.

Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$5,035, or \$95 per product.

#### Authority for This Rulemaking

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

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

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

### Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

**Diamond Aircraft Industries GmbH:** Docket No. FAA–2019–0203; Product Identifier 2018–CE–052–AD.

### (a) Comments Due Date

We must receive comments by May 17, 2019.

### (b) Affected ADs

None.

### (c) Applicability

This AD applies to Diamond Aircraft Industries GmbH (Diamond) Model DA 42 NG and Model DA 42 M–NG airplanes, serial numbers 42.N202, 42.N203, 42.N205 through 42.N207, 42.N210 through 42.N214, 42.N229 through 42.N338, 42.N340, 42.MN055, 42.MN057, and 42.MN058, certificated in any category.

### (d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

### (e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The unsafe condition reported by the MCAI is insufficient clearance of the gust lock mounts on the pilot side rudder pedals. We are issuing this AD to prevent restricted rudder travel, which could result in reduced control of the airplane.

### (f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD.

- (1) Within the next 100 hours time-in-service after the effective date of this AD:
  - (i) Remove the pilot (left-hand) side rudder pedal gust lock mounts in accordance with steps 1 through 5 of the Instructions in Diamond Aircraft Industries GmbH Work Instruction WI–MSB 42NG–077, dated August 20, 2018.
  - (ii) Revise the airplane flight manual (AFM) by adding the figures on page 8–11a of Diamond Aircraft Temporary Revision TR–MAM 42–1097 Gustlock on Co-Pilot Side only, Doc. #7.01.15–E, dated July 18, 2018, into Chapter 8 of the AFM.
- (2) As of the effective date of this AD, do not install on any airplane a pilot (left-hand) side rudder pedal gust lock mount.

### (g) Other FAA AD Provisions

The following provisions also apply to this AD:

- (1) *Alternative Methods of Compliance (AMOCs):* The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: [mike.kiesov@faa.gov](mailto:mike.kiesov@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

- (2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective

actions from a manufacturer, the action must instead be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA, or the European Aviation Safety Agency (EASA).

### (h) Related Information

Refer to MCAI EASA AD No. 2018–0214, dated October 4, 2018; and Diamond Mandatory Service Bulletin MSB 42NG–077, dated August 20, 2018, for related information. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2019–0203. For service information related to this AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; email: [office@diamond-air.at](mailto:office@diamond-air.at); internet: <http://www.diamondaircraft.com>. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on March 25, 2019.

### Melvin J. Johnson,

*Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR–601.*

[FR Doc. 2019–06280 Filed 4–1–19; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 610

[Docket No. FDA–2018–N–4757]

RIN 0910–AH95

### Revocation of the Test for Mycoplasma

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is proposing to amend the biologics regulations by removing the specified test for the presence of *Mycoplasma* for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. FDA is proposing this action because the existing test for *Mycoplasma* is restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the specific method to test for *Mycoplasma* provides flexibility for accommodating new and evolving technology and capabilities without

diminishing public health protections. This action is part of FDA's implementation of Executive Orders 13771 and 13777. Under these Executive orders, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

**DATES:** Submit either electronic or written comments on the proposed rule by June 17, 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 June 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets

Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2018-N-4757 for "Revocation of the Test for *Mycoplasma*." 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:** Tami Belouin, 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:

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#### I. Executive Summary

##### A. Purpose of the Proposed Rule

FDA proposes to remove the regulation requiring a specified test for the presence of *Mycoplasma* for live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures because the regulation is restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the required test for *Mycoplasma* provides flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections.

##### B. Summary of the Major Provisions of the Proposed Rule

The proposed rule removes § 610.30 (21 CFR 610.30), which details the method for *Mycoplasma* testing of samples of the virus harvest pool and control fluid pool of live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures.

##### C. Legal Authority

FDA is taking this action under the biological products provisions of the Public Health Service Act (the PHS Act), and the drugs and general

administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

#### D. Costs and Benefits

Because this proposed rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

## II. Background

### A. Introduction

On February 24, 2017, Executive Order 13777, "Enforcing the Regulatory Reform Agenda" (<https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda>, 82 FR 12285; March 1, 2017) was issued. One of the provisions in the Executive order requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is proposing to revoke a regulation as specified in this proposed rule.

### B. Need for Regulation

It has become increasingly clear that the test for *Mycoplasma* requirements is too restrictive for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures because they specify particular methodologies when alternatives may be available that provide the same or greater level of assurance of safety. Modifications to mycoplasma testing described in § 610.30 must meet the requirements of 21 CFR 610.9.

Thus, the Agency believes that the regulation may no longer reflect the current testing procedures as a general matter and that it is more appropriate, flexible, and efficient to identify appropriate testing requirements for particular products in the biologics license application (BLA).

This proposed rule would remove the specified test for the presence of *Mycoplasma* to provide flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections. Removal of this regulation would allow manufacturers of live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures to select the most scientifically appropriate *Mycoplasma* testing method to assure the safety, purity, and potency of their vaccines.

These newer technologies can result in higher sensitivity and specificity of

*Mycoplasma* detection and could reduce the time required to complete testing for *Mycoplasma*. Removal of this regulation would not remove *Mycoplasma* testing requirements specified in individual BLAs. A manufacturer of a live virus vaccine produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures would continue to be required to follow the *Mycoplasma* test requirements specified in its BLA, unless the BLA were revised to modify or replace the test through a supplement in accordance with § 601.12(c) (21 CFR 601.12(c)). FDA would review proposed changes to a manufacturer's approved biologics license in the context of that particular application to ensure that any such action is appropriate.

The proposed rule, if finalized, will remove the regulation; however, a manufacturer would continue to be required to test for *Mycoplasma* as specified in its BLA. If finalized, this action will provide regulated industry with flexibility, as appropriate, to employ advances in science and technology as they become available, without diminishing public health protections. As appropriate, the Agency will describe the appropriate tests for particular products in manufacturers' BLAs.

## III. Legal Authority

FDA is issuing this proposed rule under the biological products provisions of the PHS Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, and potent, and prevent the introduction, transmission, and spread of communicable disease.

## IV. Description of the Proposed Rule

### A. Scope

The test for *Mycoplasma* in § 610.30 is intended to ensure that live virus vaccines produced from in vitro living cell cultures, and inactivated virus vaccines produced from such living cell cultures do not contain *Mycoplasma*. Currently the regulation details the method for *Mycoplasma* testing of samples of the virus harvest pool and control fluid pool of live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. Removal of this regulation would eliminate a restrictive and duplicative

requirement and accommodate new and evolving technology.

We are proposing to remove the specified test for the presence of *Mycoplasma* for live virus vaccines produced from in vitro living cell cultures and inactivated virus vaccines produced from such living cell cultures. FDA is proposing this action because the existing specified test for the presence of *Mycoplasma* is restrictive and duplicative of requirements that are also specified in the BLA. This change is intended to remove restrictive or duplicative requirements and accommodate new and evolving technology and capabilities without diminishing public health protections. Removal of this regulation would not remove *Mycoplasma* testing requirements specified in individual BLAs. A biological product manufacturer would continue to be required to follow the *Mycoplasma* testing requirements specified in its BLA unless the BLA were revised to modify or replace the test through a supplement in accordance with § 601.12(c). FDA would review proposed changes to a manufacturer's approved biologics license in the context of that particular license to ensure that any such action is appropriate.

FDA is proposing to remove the requirements contained in § 610.30 from the regulations. As a result of removing § 610.30, we would also remove and reserve 21 CFR part 610, subpart D. FDA is proposing this action because the testing method described in the regulation is restrictive and more sensitive and specific testing methods are now available.

### B. Appropriate Controls Would Remain in Place

FDA believes that if this rulemaking becomes finalized as proposed, we would be able to continue to ensure that appropriate controls remain in place. If the proposed rule is finalized and the regulation calling for a specific test for *Mycoplasma* is eliminated, manufacturers would continue to be required to perform a test for *Mycoplasma* described in their BLAs for their licensed live virus vaccines produced from in vitro living cell cultures and their inactivated virus vaccines produced from such cultures. Such requirement would remain in effect unless the BLA were revised to modify or replace the test through a supplement in accordance with § 601.12(c). FDA would review proposed changes to a manufacturer's approved biologics license in the context of that particular license to

ensure that any such action is appropriate.

#### V. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the **Federal Register**.

#### VI. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule would increase flexibility and does not add any new regulatory responsibilities, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We believe industry will largely maintain their current practices following the removal of § 610.30 Test for *Mycoplasma*. Although manufacturers of live virus vaccines and

inactivated virus vaccines produced from in vitro living cell cultures may experience some unquantifiable cost savings from streamlining their testing procedures, we predict no quantifiable cost savings. FDA will also maintain its current practices, similarly generating no quantifiable cost savings. Therefore, we expect this proposed rule to be cost neutral.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

#### VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) 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.

#### VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

#### XI. Reference

The following reference is on display at 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/Economics Staff, “Elimination of 21 CFR 610.30 Test for *Mycoplasma*, Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,” 2018. (Available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.)

#### List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 610 be amended as follows:

#### PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

- 1. The authority citation for part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

#### Subpart D—[Removed and Reserved]

- 2. Remove and reserve subpart D, consisting of § 610.30.

Dated: March 26, 2018.

**Scott Gottlieb,**

*Commissioner of Food and Drugs.*

[FR Doc. 2019–06188 Filed 4–1–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2018–1057]

RIN 1625–AA00

#### Safety Zone; Gastineau Channel, Juneau, AK

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to modify an existing safety zone for certain waters of the Gastineau Channel. This action is necessary to provide for safety of vessels anchoring on these navigable waters. This proposed rulemaking would prohibit vessels, other than large passenger vessels from anchoring within the safety zone without the express consent from the Captain of the Port, Southeast Alaska, or a designated representative. We invite your comments on this proposed rulemaking and are particularly interested in any potential impact to underwater cables in the Gastineau Channel affected by this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before April 6, 2019.

**ADDRESSES:** You may submit comments identified by docket number USCG–2018–1057 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** LT Kristi Sloane, Sector Juneau, Waterways Management Division, U.S. Coast Guard, at telephone number 907–463–2846 or email to [D17-SMB-Sector-Juneau-WWM@uscg.mil](mailto:D17-SMB-Sector-Juneau-WWM@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Table of Abbreviations**

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 § Section  
 U.S.C. United States Code

##### **II. Background, Purpose, and Legal Basis**

The Coast Guard recently conducted a Waterways Analysis and Management System (WAMS) study for the Gastineau Channel. The study identified a need to

modify an existing safety zone for certain waters of the Gastineau Channel to improve safety of large passenger vessels anchoring within the safety zone. The Captain of the Port, Southeast Alaska, (COTP) has determined that modification of the existing safety zone is necessary to improve the safety of large passenger vessels anchoring in the Gastineau Channel safety zone.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the safety zone. The Coast Guard is proposing this rulemaking under authority in 33 U.S.C. 1231.

##### **III. Discussion of Proposed Rule**

The COTP is proposing to amend 33 CFR 165.1702 by way of expanding the existing safety zone in order to improve safety of large passenger vessels anchoring in the Gastineau Channel. The proposed safety zone would extend the existing safety zone approximately 300 yards at the northernmost end of the safety zone. All vessels may transit or navigate within the safety zone. No vessels, other than large passenger vessels may anchor within the safety zone without the express consent from the Captain of the Port, Southeast Alaska or a designated representative. The regulatory text we are proposing appears at the end of this document.

##### **IV. Regulatory Analyses**

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

###### *A. Regulatory Planning and Review*

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

This regulatory action determination is based on a premise that all vessels may transit or navigate within the proposed safety zone.

###### *B. Impact on Small Entities*

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

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES** section) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

###### *C. Collection of Information*

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

###### *D. Federalism and Indian Tribal Governments*

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is

consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

#### *E. Unfunded Mandates Reform Act*

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

#### *F. Environment*

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone that allows all vessels to transit or navigate within the safety zone but prohibits vessels, other than large passenger vessels from anchoring within the safety zone without the express consent from the Captain of the Port, Southeast Alaska or a designated representative. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01 We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

### **V. Public Participation and Request for Comments**

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <https://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

#### **List of Subjects in 33 CFR Part 165**

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

#### **PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS.**

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

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Revise § 165.1702 to read as follows:

#### **§ 165.1702 Gastineau Channel, Juneau, Alaska-safety zone.**

(a) The waters within the following boundaries are a safety zone: All waters

eastward to shore from a line beginning at Gastineau Channel Light 4 (LLNR 23695) in position 58°17.82' N, 134°25.36' W, in the direction of 130° True to Rock Dump Lighted Buoy 2A (LLNR 23685) at position 58°17.14' N, 134°23.84' W.

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

(1) *A large passenger vessel* for the purpose of this regulation are cruise ships and ferries.

(2) *Cruise ship* means any vessel over 100 gross registered tons, carrying more than 12 passengers for hire which makes voyages lasting 24 hours, of which any part is on high seas. Passengers from cruise ships are embarked or disembarked in the U.S. or its territories. Cruise ships do not include ferries that hold Coast Guard Certificates of Inspection endorsed for “Lakes, Bays, And Sounds”, that transit international waters for only short periods of time on frequent schedules.

(3) *Ferry* means a vessel which is limited in its use to the carriage of deck passengers or vehicles or both, operates on a short run on a frequent schedule between two or more points over the most direct water route, other than in ocean or coastwise service.

(c) *Special Regulations.* (1) All vessels may transit or navigate within the safety zone.

(2) No vessels, other than a large passenger vessel may anchor within the safety zone without the express consent from the Captain of the Port, Southeast Alaska.

Dated: March 7, 2019.

**Stephen R. White,**

*Capt., U.S. Coast Guard, Captain of the Port, Southeast Alaska.*

[FR Doc. 2019–06375 Filed 4–1–19; 8:45 am]

**BILLING CODE 9110–04–P**

### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Parts 260, 261, and 266**

[EPA–HQ–OLEM–2018–0830; FRL–9991–43–OLEM]

**RIN 2050–AG93**

#### **Modernizing Ignitable Liquids Determinations**

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA or the Agency) is proposing to update the regulations for the identification of ignitable hazardous waste under the Resource Conservation

and Recovery Act (RCRA) and to modernize the RCRA test methods that currently require the use of mercury thermometers. These proposed revisions would provide greater clarity to hazardous waste identification, provide flexibility in testing requirements, improve environmental compliance, and, thereby, enhance protection of human health and the environment.

**DATES:** Comments must be received on or before June 3, 2019.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OLEM-2018-0830, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** Daniel Fagnant, Office of Land and Emergency Management (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 703-308-0319; email address: [fagnant.daniel@epa.gov](mailto:fagnant.daniel@epa.gov) or Melissa Kaps, Office of Land and Emergency Management (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 703-308-6787; email address: [kaps.melissa@epa.gov](mailto:kaps.melissa@epa.gov).

**SUPPLEMENTARY INFORMATION:** The information presented in this preamble is organized as follows:

#### I. General Information

- A. Does this action apply to me?
- B. What action is the Agency taking?
- C. What is the Agency's authority for taking this action?
- D. What are the incremental costs and benefits of this action?

#### II. Background

- A. What is a hazardous waste?
  - B. What is the hazardous waste characteristic of ignitability?
  - C. What is the regulatory history of the ignitability characteristic?
  - D. What is a flash point and how is it measured?
  - E. What flash point test methods does EPA currently require?
  - F. What is the aqueous alcohol exclusion?
  - G. Why consider alternatives to mercury thermometers in test methods?
- III. Proposed Revisions to the Ignitability Characteristic Flash Point Test Methods
- A. Why is EPA proposing new flash point test methods for ignitable liquids?
  - B. What test method is EPA proposing to add to Method 1010A?
  - C. What test method is EPA proposing to add to Method 1020B?
  - D. How are the proposed test methods equivalent to the currently required test methods?
  - E. Why is EPA not removing the currently required flash point test methods?
- IV. Codification of Guidance Into the Ignitability Characteristic
- A. Aqueous Alcohol Exclusion
    1. Why is EPA proposing a revision to the aqueous alcohol exclusion?
    2. What are the proposed changes to the aqueous alcohol exclusion?
    3. Solicitation of Public Input on Other Changes to the Aqueous Alcohol Exclusion for Ignitability
  - B. Multiphase Testing
    1. Why is the Agency proposing a revision to codify sampling guidance for multiphase wastes?
    2. Proposed Codification of Guidance for Multiphase Waste Sampling
- V. Additional Corrections to § 261.21
- A. What are the proposed changes to the definition of ignitable compressed gas in § 261.21(a)(3)(ii)?
  - B. What are the proposed changes to § 261.21(a)(4)(i)(A)?
  - C. What are the proposed changes to the notes section of § 261.21?
- VI. Revision to Mercury Thermometer Requirements in the Air Sampling and Stack Emissions Methods
- A. Why is EPA proposing revisions to the air sampling and stack emissions methods?
  - B. Proposed Changes to Mercury Thermometer Requirements in SW-846 Method-Defined Parameter Air Sampling and Stack Emissions Methods
- VII. Incorporation by Reference
- VIII. State Authorization
- A. Applicability of Proposed Rule in Authorized States
  - B. Effect on State Authorization
- IX. Statutory and Executive Orders Reviews
- A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  - B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs
  - C. Paperwork Reduction Act (PRA)
  - D. Regulatory Flexibility Act (RFA)
  - E. Unfunded Mandates Reform Act (UMRA)

- F. Executive Order 13132: Federalism
- G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
- J. National Technology Transfer and Advancement Act (NTTAA)
- K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

#### I. General Information

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

The proposed rule to update the test methods for determining if a liquid waste is ignitable under the ignitability characteristic may potentially affect any entity (*e.g.*, generator, laboratory) that currently conducts flash point testing using either SW-846 Method 1010A (Pensky-Martens) or Method 1020B (Setaflash). The rule may also affect any entity (*e.g.*, generator, laboratory, combustor) that uses SW-846 air sampling and stack emissions Methods 0010, 0011, 0020, 0023A, or 0051. EPA does not expect the other parts of this proposed action (*i.e.*, changes to aqueous alcohol exclusion, addition of sampling guidelines for multiphase mixtures, and technical edits) to affect any entity because they do not create new requirements or change existing requirements.

The universe of facilities affected by the proposed updates to the ignitability test methods and SW-846 air sampling and stack emissions methods includes: (1) Commercial laboratories, (2) EPA laboratories, and (3) state laboratories. EPA identified 217 unique commercial laboratories that conduct ignitability testing under either Method 1010A or 1020. EPA identified an additional 18 commercial laboratories accredited to conduct any of the air sampling and stack emissions methods that would be updated under this proposed rule, for a total of 235 commercial labs affected by the rule. These 235 total laboratories are part of 177 unique firms, including several large commercial laboratories with multiple locations. EPA estimates that the total number of laboratories, including 20 state and nine federal laboratories, potentially affected by this rule is 264. The analysis used to identify the potential universe for this proposed rule can be found in EPA's *Regulatory Impact Analysis of the Modernization of Ignitable Liquid Determination Rule*, which is in the docket.

This discussion is not intended to be exhaustive but rather provides a guide for readers regarding entities likely to be regulated by this action. This discussion lists the types of entities that EPA is now aware could potentially be regulated by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

#### *B. What action is the Agency taking?*

First, EPA proposes to update the flash point test methods required for determining if a liquid waste is an ignitable hazardous waste. Second, EPA is proposing to codify existing guidance regarding the regulatory exclusion in the ignitable characteristic for aqueous liquids containing alcohols and is requesting comment on whether additional changes may be warranted. Third, EPA is proposing to codify existing sampling guidance regarding waste mixtures having multiple phases when determining whether a waste exhibits the ignitability characteristic. Fourth, EPA is proposing to update cross references to Department of Transportation regulations and to remove obsolete information. Finally, EPA is proposing to provide alternatives to the use of mercury thermometers in the air sampling and stack emissions methods in *Test Methods for Evaluating Solid Waste: Physical/Chemical Methods* (SW-846). Adding the option of using non-mercury thermometers in place of mercury thermometers would provide the regulated community with increased flexibility in their implementation of these required test methods. The use of alternatives to mercury thermometers is consistent with previous Agency actions and helps achieve the Agency's goal of minimizing the use of mercury.

The EPA is proposing and requesting comment on revisions to modernize the ignitability flash point test methods (Methods 1010A and 1020B) and air sampling and stack emissions methods (Methods 0010, 0011, 0020, 0023A, and 0051) to allow the use of non-mercury thermometers. The Agency is also proposing to update the ignitability regulation (40 CFR 261.21) by codifying guidance for aqueous alcohol solutions and multiphase mixtures, as well as making technical corrections. EPA expects this proposed rulemaking to improve hazardous waste identification, reduce testing costs, improve laboratory safety, and improve environmental compliance, thereby enhancing protection of human health and the environment.

#### *C. What is the Agency's authority for taking this action?*

The authority to propose this rule can be found in sections 1002, 1006, 2002, 3001–3009, 3013, and 3017 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6901, 6905, 6912, 6921–6929, 6934, and 6938.

#### *D. What are the incremental costs and benefits of this action?*

EPA prepared an economic analysis of the potential costs and benefits associated with this proposed action. The *Regulatory Impact Analysis of the Modernization of Ignitable Liquid Determinations Rule* is available in the docket. The proposed rule will modify SW-846 test methods while also retaining the current procedures to provide entities increased flexibility. For the purpose of the analysis, EPA assumes that every facility that currently conducts flash point testing: (1) Is compliant with the current test methods, (2) will adopt the updated test methods if cost effective, and (3) will continue to conduct flash point testing. The analysis indicates that the rule, as proposed, is projected to result in annualized cost savings of about \$78,500 to \$477,000 (based on a discount rate of 7 percent). The net present value of costs over 20 years is estimated to be a cost savings of \$832,000 to \$5 million (seven percent discount rate). EPA's analysis shows qualitative benefits to human health and the environment through the reduced use of mercury thermometers.

## **II. Background**

#### *A. What is a hazardous waste?*

Subtitle C of RCRA and its implementing regulations establish a cradle-to-grave regulatory management scheme for certain solid wastes that qualify as hazardous wastes. RCRA defines solid waste as “any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material \* \* \*.” (See RCRA 1004(27), 42 U.S.C. 6903(27).) EPA has further defined the term solid waste for purposes of its RCRA hazardous waste regulations (40 CFR 261.2). To be considered a hazardous waste, a material first must be classified as a solid waste. Under EPA's regulations, generators of solid waste are required to determine whether their wastes are

hazardous wastes (40 CFR 262.11). A solid waste is a hazardous waste if it exhibits any of the four characteristics of ignitability, corrosivity, reactivity, or toxicity (40 CFR 261.20–.24), or is a listed waste (40 CFR 261.30–.33). Listed wastes include wastes from non-specific sources, such as spent solvents; by-products from specific industries; and discarded, unused commercial chemical products.

#### *B. What is the hazardous waste characteristic of ignitability?*

The characteristic of ignitability (40 CFR 261.21) identifies solid waste as hazardous based on the properties of the waste that give it the potential to cause harm to human health or the environment through direct or indirect fire hazard, including contributing to or causing landfill fires. Waste that is identified as hazardous pursuant to 40 CFR 261.21 has the EPA Hazardous Waste Number of D001. Ignitable hazardous waste (D001) is regulated to minimize its opportunity to cause or contribute to fires during routine waste management activities. Solid wastes that are regulated as ignitable hazardous waste include: (1) Certain liquids with flash points below 60 °C (140 °F); (2) non-liquid substances that are capable, under specified conditions, of causing fire through friction, absorption of moisture, or spontaneous chemical changes and, when ignited, burns so vigorously and persistently that they create a hazard; (3) ignitable compressed gases; and (4) oxidizers.

#### *C. What is the regulatory history of the ignitability characteristic?*

The ignitability characteristic was originally proposed in 1978 (43 FR 58945) with an objective of identifying wastes that present a fire hazard due to being ignitable under routine waste disposal and storage conditions. The ignitability characteristic was finalized in 1980 when EPA promulgated the first phase of regulations under Subtitle C of RCRA to protect human health and the environment from the improper management of hazardous waste (45 FR 33066, May 19, 1980). These regulations included 40 CFR part 261, which in part, defined the ignitability characteristic and incorporated by reference ASTM<sup>1</sup> D 93–79 (Pensky-Martens) and ASTM D 3278–78 (Setaflash) as the required tests for ignitable liquid hazardous waste determinations. In a 1981 revision, EPA

<sup>1</sup> ASTM International (ASTM) is a nonprofit organization, made up of producers, users, consumers, government, and academia, that develops and publishes consensus-based standards (<https://www.astm.org/>).

revised SW-846 Method 1010 to allow the use of D 93-79 or D 93-80 (46 FR 35246, July 7, 1981).

ASTM standards D 3278-78, D 93-79, and D 93-80 were the methods available for flash point testing at the time of the 1980 and 1981 rulemakings. Since that time, ASTM International (ASTM) has updated D 93 and D 3278 multiple times to improve the standards and incorporate new technology. EPA previously proposed to update the flash point test methods for ignitability in the 2002 proposed Methods Innovation Rule (67 FR 66252, Oct 30, 2002) by replacing ASTM standard D 3278-78 with D 3278-96 and ASTM standards D 93-79 and D 93-80 with D 93-99c. In that proposed rule, EPA also requested comment on whether D 93-00 should instead replace D 93-79 and D 93-80. The public raised concerns that the sampling procedures of the proposed versions of D 93 may lead to a loss of flammable volatile constituents from a sample due to greater headspace in the sampling container. The Agency made the decision to not revise flash point testing when the Methods Innovation Rule was finalized in 2005, agreeing with public comments that EPA further study the changes in flash point testing standards (70 FR 34550, June 14, 2005).

EPA later made corrections to the ignitability characteristic to replace obsolete references to DOT regulations related to definitions of ignitable compressed gases and oxidizers (see July 14, 2006 **Federal Register**; 71 FR 40254). That final rule amended § 261.21 by revising paragraphs (a)(3) and (a)(4) and adding notes 1 through 4 to the end of the section. No change was made to § 261.21(a)(1). The current language in § 261.21(a)(1) is substantively the same as it was in 1980.

#### *D. What is a flash point and how is it measured?*

The Kirk-Othmer Encyclopedia of Chemical Technology defines a flash point as the lowest temperature, corrected to normal atmospheric pressure (101.3kPa), at which the application of an ignition source causes the vapors of a liquid specimen to ignite under the specific conditions of the test (Solvents. Kirk-Othmer Encyclopedia of Chemical Technology. 1-40). A flash point can be measured using a specifically designed apparatus operated under specified procedures. In general, these procedures involve incrementally heating a liquid sample to a specified temperature in an open or closed cup and then exposing the vapors above the liquid to a flame or electric spark ignition source. The person performing the test looks for a

flash caused by the vapor phase igniting; if no flash is observed, the sample is heated to a higher temperature and the experiment is repeated. When used for RCRA regulatory purposes, the test is repeated until the temperature surpasses 60 °C (140 °F) using specified procedures and apparatuses to ensure that accurate and precise waste determinations are being made.

#### *E. What flash point test methods does EPA currently require?*

EPA currently requires the use of one of two flash point test methods when making an ignitability hazardous waste determination for liquid wastes, if generator knowledge is not used. (For more information on the use of generator knowledge, see Agency guidance, *Waste Analysis at Facilities that Generate, Treat, Store and Dispose of Hazardous Wastes*, available in the docket.) The required test methods to determine the method-defined parameter for the flash point of ignitable hazardous waste are SW-846 Methods 1010A and 1020B, which are listed in 40 CFR 260.11 and required by 40 CFR 261.21(a)(1). EPA requires the use of a specific method to obtain a method-defined parameter when the particular procedures and/or equipment of that method are necessary to achieve the property measurement required by regulation. Therefore, to determine whether a liquid waste is ignitable hazardous waste under RCRA (*i.e.*, has a flash point less than 60 °C (140 °F)), its flash point must be assessed according to the procedures and instrumentation set forth in Methods 1010A or 1020B. While other methods may exist that can measure the flash point of a liquid waste, only the test methods set forth in Methods 1010A or 1020B may be used for determining whether a liquid waste is ignitable under 40 CFR 261.21(a)(1). Because using Method 1010A or 1020B yields results that are driven by the particular technical specifications in those methods, the measures and outcomes from these methods are known as method-defined parameters, and their required use in section § 261.21 can only be amended through a regulatory effort.

Method 1010A is a test method for flash point measurement using a procedure and instrumentation commonly referred to as the Pensky-Martens method. Method 1010A, or the Pensky-Martens method, incorporates by reference ASTM standards D 93-79 and D 93-80. The last two digits at the end of these ASTM standards indicate the year of publication for these standards (*i.e.*, 1979 and 1980,

respectively). ASTM standard D 93 is an actively maintained standard under the ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants. The most recent update to the D 93 standard is D 93-16a, which was published in 2016.

Alternatively, SW-846 Method 1020B can be used for determining the hazardous waste characteristic of ignitability for liquids. Method 1020B is a test method for flash point measurement using the Setaflash, or small-scale closed-cup, device and method. Method 1020B incorporates by reference ASTM standard D 3278-78, which is maintained by the ASTM Committee D01 on Paint and Related Coatings, Materials, and Applications. The last update to this ASTM standard was in 1996. However, the standard was reaffirmed in 2011 as ASTM D 3278-96(2011).

In making an ignitable liquid hazardous waste determination, either the Pensky-Martens or the Setaflash method may be used for most wastes. The Pensky-Martens test is more appropriate for liquids that are nonhomogenous, form films, have high viscosities, or are slurries because it uses an instrument that can mechanically mix wastes. The Setaflash method, however, provides a practical advantage of reduced sample size and, therefore, reduced lab waste generation when compared to the Pensky-Martens method. Generators and laboratories should choose to use the test method that is most suitable to their needs.

#### *F. What is the aqueous alcohol exclusion?*

The ignitability characteristic in § 261.21(a)(1) excludes “aqueous solution[s] containing less than 24 percent alcohol by volume” from the scope of liquids subject to § 261.21. When EPA originally proposed the ignitability characteristic in 1978, the proposed rule did not contain an exclusion for aqueous alcohols (43 FR 58945). Commenters on the 1978 proposed rule “argued that the ignitability characteristic improperly includes many liquid wastes such as wine, latex paint and other water borne coatings which contain low concentrations of volatile organics such as alcohol and will consequently exhibit flash points below 100 °F but will not sustain combustion because of the high percentage of water present.” (Background Document for the Characteristic of Ignitability, US EPA, May 2, 1980, page 38.) In response, EPA modified the ignitability characteristic in the final rule with “an exclusion similar [sic] to that prescribed by DOT

[Department of Transportation] and exempt from the ignitability characteristic aqueous solutions with alcohol concentrations of less than 24 percent by volume. This exclusion will remove from the ignitability characteristic such things as wine and latex paint which flash at less than 100 °F but will not sustain combustion.” (ibid., 39.) Thus, the 1980 final rule codified the following text in the definition of ignitability at § 261.21(a)(1): “It is a liquid, other than an aqueous solution containing less than 24 percent alcohol by volume, and has a flash point less than 60 °C (140 °F).”<sup>2</sup> (45 FR 33121; May 19, 1980.)

EPA later clarified the alcohol exclusion in several ways. In the preamble to a later rulemaking (55 FR 22543, June 1, 1990), EPA stated that “the term alcohol [in § 261.21(a)(1)] refers to any alcohol or combination of alcohols” and noted that “[i]f the alcohol has been used for solvent properties and is one of the alcohols specified in EPA Hazardous Waste No. F003 or F005, the waste must be coded with these Hazardous Waste Numbers.” In addition, in 1992, the EPA clarified that the “alcohol exclusion in 40 CFR 261.21(a)(1), however, is not limited to those wastes mentioned in the May 19, 1980, **Federal Register**. It applies to all aqueous solutions containing less than 24 percent alcohol, even if additional non-alcoholic components are present.” (EPA Monthly Hotline Report, EPA530-R-92-014g, July 1992, page 3.)<sup>3</sup> In that clarification, EPA stated that the “alcohol exclusion for the ignitability characteristic was adopted from the Department of Transportation’s (DOT) definition of “combustible liquids” in 49 CFR 173.115(b). The alcohol exclusion in 49 CFR 173.115(b)(2)(ii) applies to aqueous solutions containing 24 percent or less alcohol by volume which contain no less than 50 percent water. Since EPA originally intended to be consistent with DOT regulations when promulgating the alcohol exclusion in § 261.21(a)(1), the 50 percent water stipulation may be applied to the ignitability

<sup>2</sup> Note that even if this waste stream falls within the scope of the aqueous alcohol exclusion and, thus, would not be regulated as an ignitable hazardous waste, this waste stream could still be regulated as a hazardous waste if it exhibits other hazardous characteristics or is listed. In addition, once a waste stream no longer meets the requirements of the exclusion or is likely to not meet the requirements during normal management (e.g., the water or alcohol content changed), the waste would be subject to regulation under the ignitability characteristic.

<sup>3</sup> A copy of this Question and Answer has been placed into the docket for this proposal. A version is also available at [www.epa.gov/rcraonline](http://www.epa.gov/rcraonline), RCRA Online Number 13548.

characteristic.”<sup>4</sup> Thus, for the purpose of the ignitability characteristic in § 261.21(a)(1), EPA stated that “aqueous” means a “solution continuing at least 50 percent water by weight.” (ibid., 4.)

#### G. Why consider alternatives to mercury thermometers in test methods?

Today, EPA is proposing to remove the requirement to use mercury thermometers in several EPA analytical methods by revising the method or by adding modern alternative methods that may be used. Because of its unique properties, elemental mercury has been used in many applications, including thermometers, fluorescent light bulbs, and some electrical switches. However, mercury from these devices can enter the environment through breakage or spills during use and during recycling or disposal. Mercury is a potent neurotoxin with a variety of well-documented negative health effects. For more information on the negative health effects of mercury exposure, see <https://www.epa.gov/mercury/health-effects-exposures-mercury#self>.

Government agencies continue to phase out the use of mercury devices, including efforts by EPA (see 76 FR 2056, January 12, 2011; 77 FR 2456, January 18, 2012; and the September 30, 2008 memorandum, Phasing Out Mercury Filled Thermometers<sup>5</sup>), the National Institute of Standards and Technology (NIST) (see *User-Friendly Guidance on the Replacement of Mercury Thermometers*<sup>6</sup>), and the Agency for Toxic Substances and Disease Registry (ATSDR) (see report on *Children’s Exposure to Elemental Mercury: A National Review of Exposure Events*<sup>7</sup>). Organizations, including ASTM International (see ASTM and the Mercury Initiative<sup>8</sup>) and the United Nations Environment Programme (UNEP) (see Minamata Convention<sup>9</sup>), have also worked to phase out mercury

<sup>4</sup> In developing this proposed rule, EPA reviewed how the ignitability characteristic’s aqueous alcohol exclusion related to the alcohol exclusion under DOT’s Hazardous Materials Regulations (HMR). A summary of DOT’s HMR’s exemption of alcoholic beverages and aqueous solutions of alcohol has been placed into the docket for reference.

<sup>5</sup> This memorandum is available at <https://www.epa.gov/mercury/2008-memo-requiring-all-epa-labs-phase-out-use-mercury-filled-thermometers> and in the docket.

<sup>6</sup> This document is available at <https://www.epa.gov/sites/production/files/2015-10/documents/nistuserfriendlyguide.pdf> and in the docket.

<sup>7</sup> This report is available at [https://www.atsdr.cdc.gov/mercury/mercury\\_report.html](https://www.atsdr.cdc.gov/mercury/mercury_report.html) and in the docket.

<sup>8</sup> See [https://www.astm.org/SNEWS/SO\\_2008/mercury\\_so08.html](https://www.astm.org/SNEWS/SO_2008/mercury_so08.html) and the docket.

<sup>9</sup> See <http://www.mercuryconvention.org/>.

thermometer usage. EPA maintains information on efforts to reduce mercury exposures and to address mercury pollution in the environment at <https://www.epa.gov/mercury>. In the majority of uses, mercury thermometers can be replaced with safer, technically appropriate, readily available non-mercury temperature measurement devices (Ripple and Strouse J. ASTM International 2005).

### III. Proposed Revisions to the Ignitability Characteristic Flash Point Test Methods

#### A. Why is EPA proposing new flash point test methods for ignitable liquids?

Although the flash point test methods currently required by § 261.21(a)(1) provide accurate determinations of whether a liquid waste is characteristic for ignitability, these methods were published about 40 years ago, and newer technology is now available. As explained in Section II.E. in this notice, SW-846 Method 1010A currently incorporates by reference ASTM standards D 93-79 and D 93-80, which are known as the Pensky-Martens method. SW-846 Method 1020B currently incorporates by reference ASTM standard D 3278-78, otherwise known as the Setaflash method. These test methods represented technology and best practices developed in 1978, 1979, and 1980. Since then, the ASTM committees that maintain these standards have updated these test methods to incorporate modernized technology and practices, but the RCRA regulations still require the use of the 1978, 1979, and 1980 versions.

Due to the scientific and technological advances over the last few decades, these methods have become outdated and their use presents several challenges to the regulated community. For instance, these standards require mercury thermometers, which are being phased out because of the environmental health and safety concerns of mercury. The Agency’s mercury thermometer requirements have become more difficult to meet as organizations, such as NIST (NIST, 2011), discontinue calibration services for mercury thermometers; consensus-based bodies, such as ASTM (ASTM, 2008), phase out mercury thermometers from their standards; and instrument manufacturers phase out mercury thermometers from commercially available equipment. As part of its efforts to reduce mercury usage and release, and in the interest of providing the regulated community with modern, readily available options for compliance, EPA has already revised

SW-846 methods that require the use of mercury thermometers to allow for the use of non-mercury-containing temperature measuring devices (77 FR 2456, Jan 18, 2012; 79 FR 11228, Feb 27, 2014).

The decreased use of mercury thermometers and new technology in modern instrumentation combined with the decreased availability of calibration services limit commercially available flash point devices that meet the current EPA testing requirements for ignitable waste. First, the flash point standards required by EPA use reference materials that, as EPA understands, are no longer commercially available as certified reference materials, such as para-xylene for D 3278-78. Second, new technologies, such as electric spark ignition sources in place of flame ignition sources, offer improved lab safety and are available in modern instruments. Third, the Agency believes that new instruments may not be able to increase temperature at the specified rate (temperature ramping rate) in SW-846 Method 1020B.

EPA is proposing to revise the existing required Flash Point Test Methods 1010A and 1020B by adding modern consensus-based standards that reflect the improvements and modernization of flash point testing that has occurred since 1978 to the methods currently required by 261.21(a). EPA understands that many generators and laboratories already have instrumentation capable of modern flash point testing. Therefore, the proposed update adds the flexibility of using modern test methods, provides the potential for cost savings, and enhances the protection of human health and the environment while providing equivalent results (See Section III.D. for information on how the proposed test methods are equivalent to the currently required test methods).

*B. What test method is EPA proposing to add to Method 1010A?*

EPA is proposing to revise 40 CFR 261.21 and update Method 1010A to Method 1010B to incorporate by reference ASTM standard D 8175-18 as an alternative to ASTM standards D 93-79 and D 93-80 (Pensky-Martens method) (see Table 1). The D 8175-18 standard is maintained by the ASTM Committee D34 on Waste Management, with whom the Agency worked to modify the existing D 93-16 standard for waste testing. The creation of the D 8175-18 standard utilized the existing knowledge and practices of the flash point testing community to develop a standard specifically suited for flash point testing of waste matrices.

The Agency initially considered proposing to incorporate by reference ASTM standard D 93-16 as a required flash point test method. ASTM standard D 93, has been updated numerous times between 1980 and 2017. The 1979, 1980, 2016, and 2017 versions of D 93 all achieve the same fundamental measurement; the newest versions incorporate newer technology, provide more detailed procedures, and include quality control measures, such as instrument verification using certified reference materials. However, the D 93-16 standard was written for the testing of petroleum products, and EPA, after reviewing the standard, had concerns that the standard was not ideally suited for flash point testing of waste forms. The matrices of discarded chemicals, lab wastes, liquids from emergency response, free products, and other wastes that might make up a waste mixture are often more complex and varied than petroleum products. The Agency is concerned about the appropriateness of some aspects of the D 93-16 sampling procedures when applied to waste analysis. The D 93-16 standards were developed primarily to

test the flash point of products while RCRA testing requirements are often for more complex mixtures. For example, heating a sample to lower the viscosity before placing it in the closed cup device for measurement of the flash point may produce results that are not representative when testing waste mixtures with relatively small concentrations of volatile components that easily ignite and readily evaporate at elevated temperatures. The Agency notes that the public raised similar concerns in comments regarding the Agency's proposal to incorporate D 93-99c by reference as part of the Methods Innovation Rule (See comments by the American Chemistry Council, EPA Docket Number EPA-HQ-RCRA-2002-0025). The D 93-16 standard is also designed to measure petroleum products in a temperature range from 40 °C to 370 °C. As the regulatory criteria for flash point of ignitable liquids is 60 °C and below, EPA worked with ASTM to modify the D 93-16 test procedure to measure flash points of waste matrices in a narrower temperature range and closer to room temperature. The lower but narrower temperature range required for RCRA ignitability testing also allows for a slower temperature ramp rate in the method. The Agency notes that it is possible that the lowest temperature of the apparatus is significantly higher than the actual flash point of the sample. Some liquids such as gasoline, pentane, hexane, natural gas condensate, drip oil, etc. have flash points below -20 C, the lower limit of the small scale closed cup test method. Conditions can exceed the fire point (see ASTM D92) and a significant enlargement of the test flame is observed. In such situations, it is to be concluded that the flash point is below the range of the tester and hence below 60 C.

TABLE 1—SUMMARY OF CURRENT AND PROPOSED SW-846 FLASH POINT TESTS AND THE ASTM STANDARDS INCORPORATED BY REFERENCE

ASTM Standard incorporated by reference	Common name	Status	EPA SW-846 method number	Publication year
D 93-79 .....	Pensky-Martens .....	Current flash point test method used in §261.21(a)(1).	1010A	1979
D 93-80 .....	Pensky-Martens .....	Current flash point test method used in §261.21(a)(1).	1010A	1980
D 8175-18 .....	Pensky-Martens .....	Proposed modern, alternative flash point test method.	1010B	2018
D 3278-78 .....	Setaflash, Small Scale Closed Cup .....	Current flash point test method used in §261.21(a)(1).	1020B	1978
D 8174-18 .....	Setaflash, Small Scale Closed Cup .....	Proposed modern, alternative flash point test method.	1020C	2018

*C. What test method is EPA proposing to add to Method 1020B?*

EPA similarly worked with ASTM to modify the current version of the small-scale closed-cup flash point test. EPA is proposing to revise § 261.21 and update Method 1020B to Method 1020C, incorporating by reference the resulting ASTM standard D 8174–18 as an alternative to ASTM standard D 3278–78 (Setaflash method) (see Table 1). The D 8174–18 standard is an updated version of the D 3828–16a standard that has been modified to be more appropriate for waste testing. EPA first considered incorporating by reference D 3278–96(2011), which is the most current version of the standard that is in Method 1020B. However, this standard does not use the most modern technology available for Setaflash closed-cup testing, having been last updated in 1996 (and last reaffirmed in 2011). As ASTM has multiple standards for closed-cup flash point testing, EPA also considered the suitability of ASTM standards D 7236–16 and D 3828–16a. Due to EPA's understanding that D 3828 is a preferred method in the analytical community, EPA focused on ASTM standard D 3828–16a as a new test for ignitable liquids. After further review of ASTM D 3828–16a standard, the Agency identified concerns with the sampling procedures similar to the Agency's concerns with D 93–16 as stated in Section III.B. The sampling procedures in 3828–16a are refined and optimized for petroleum products. Waste matrices can be mixtures of a wide variety of chemical compounds with varying physical properties and may present sampling challenges not often found in petroleum products. As a result, EPA worked with ASTM to adapt the standard to waste samples.

Additionally, EPA was interested in a testing procedure that minimized sampling requirements and waste generation. The use of a finite flash method would require that samples with unknown flash point temperatures be measured in a series of tests until a flash was detected. Each test in the series would require a new sample be placed in the tester, increasing the amount of sample required for analysis and waste generated by testing. Therefore, EPA worked with ASTM to develop a modified version of ASTM standard D 3828–16a that also includes a non-mandatory ramp test. This ramp test procedure (found in the appendix of D 8174–18) can be used to determine an estimated flash point when working with an unknown sample. The estimated flash point can then be used to perform the finite flash test

procedure, limiting the total number of tests needed when the expected flash point of a sample is not known.

*D. How are the proposed test methods equivalent to the currently required test methods?*

Technical changes between the currently required SW–846 Methods 1010A and 1020B and the proposed test methods include the allowance for an automatic method with electronic flash point detection, the option to use a flame ignition source or an electric ignition source, and use of non-mercury temperature devices. The changes in instrumentation that have occurred over time as new technology was developed present opportunities for improvements to a method but also may affect precision, accuracy, or bias of an instrument or method. In the process of adapting these new technologies, ASTM and other organizations have conducted a number of studies to verify that these technological changes present equivalent testing results, as discussed below.

The use of automated instrumentation for flash point testing has been a widely accepted practice for decades. In 1992, ASTM completed a round robin study (see Research Report S15–1008 in docket) using ASTM standards D 92 and D 93 to determine the precision and accuracy of automatic and manual flash point instruments. This round robin study found no statistical difference between the reproducibility variances of automatic and manual Pensky-Martens flash point methods.

The use of electric ignition sources in flash point testing improves lab safety. The Energy Institute funded a round robin study to determine the precision for ASTM D 3828–9 using both gas and electric igniters (see Energy Institute Research Report, August 15, 2010 in docket). The round robin study found that while there was bias between the electric and gas ignition sources, the bias was small relative to the repeatability of the method. ASTM took this information into consideration and decided to publish a combined precision applicable to both gas and electric igniters for ASTM standard D 3828.

Both of the new ASTM standards that will be incorporated by reference, D 8175–18 and D 8174–18, allow for the use of temperature measuring devices that are either digital or liquid-in-glass. The digital temperature measuring devices and liquid-in-glass thermometers must meet the specifications listed in Annex A1 and A2 of D 8175–18 and Annex A4 of D 8174–18. These performance-based

specifications may allow for the use of mercury-containing thermometers but do not require them. The performance requirements of temperature measurement devices are set by manufacturers to meet certification standards set by NIST and other standards organizations. The use of calibrated and certified non-mercury temperature measurement devices in flash point testing is expected to provide equivalent results (See User Friendly Guidance on the Replacement of Mercury Thermometers from NIST/EPA in docket).

The changes in instrumentation to incorporate new technology are already reflected in the modern versions of the ASTM standards that are currently required by EPA for flash point testing pursuant to 261.21 (e.g., modern versions of D 93–79, such as D 93–16a, have electric ignition sources). The repeatability and reproducibility of the modern standards are similar to that of the standards currently required by EPA.<sup>10</sup> This similarity, for the purposes of flash point testing, indicates that the results from either test method should be similar.

For example, ASTM standard D 93–80 lists a repeatability of 2 °C and a reproducibility of 3.5 °C for flash point measurements of 104 °C and under. For modern versions of D 93, repeatability and reproducibility are dependent upon the flash point temperature measured. Therefore, using EPA's regulatory value for flash point of 60 °C in the temperature-dependent equation given by ASTM D 93–16, repeatability is 1.74 °C and reproducibility is 4.26 °C. ASTM standard D 3278–78 gives a repeatability of 1.7 °C and a reproducibility of 3.3 °C. D 3278–96(11), which is the modern version of D 3278–78, lists a repeatability of 1.7 °C and a reproducibility of 3.3 °C. The similar values for repeatability and reproducibility in the modern standards and the 1978 to 1980 standards that EPA currently requires shows that the accuracy of these methods has remained relatively unchanged despite the adoption of new technology into the standard as discussed above.

These precision and accuracy statements from ASTM are based on testing relatively pure reference chemicals. To confirm these results for more complex waste forms (e.g., those

<sup>10</sup> Repeatability and Reproducibility are terms defined by ASTM and other organizations. Repeatability is precision determined from multiple test results by a single, well trained operator in a single lab with one set of equipment. Reproducibility is precision determined from multiple tests in several laboratories. See ASTM E177–14 for more information.

consisting of multiple components and multiple phases), a single lab study was conducted. In ASTM standards D 8175–18 and D 8174–18, a single lab study using simulated waste matrices determined repeatability for these standards. The simulated waste matrices were single phases consisting of an equal volume mixture of xylenes and 1-butanol, a mixture (by volume) of 60% 1-butanol and 40% n-decane, a mixture (by volume) of 70% n-decane and 30% n-undecane, and a mixture (by volume) of 10% acetone and 90% n-heptane. A multiphase mixture (by volume) of 50% diesel, 47.5% water, and 2.5% acetone was also studied (see D 8175–18 and D 8174–18 in the docket for specific results). Based on these studies, D 8175–18 repeatability is between 0.88 °C and 2.26 °C for the five samples tested. D 8174–18 repeatability is between 0.88 °C and 2.34 °C for the five waste forms tested. The repeatability values of D 8175–18 and D 8174–18 are consistent with the stated repeatability of the ASTM standards currently required by SW–846 Methods 1010A and 1020B (i.e., ASTM standards D 3278–78, D 93–79, and D 93–80). EPA understands that future updates to ASTM standards D 8175–18 and D 8174–18 will have more robust precision and accuracy values when ASTM completes interlaboratory validation of the methods. EPA will update the regulation or revisit the accuracy of these test methods, if necessary.

*E. Why is EPA not removing the currently required flash point test methods?*

ASTM standards D 93–79, D 93–80, and D 3278–78 remain technically acceptable methods for determinations of flash point for ignitable liquids. The Agency strongly encourages generators and laboratories to use alternatives to mercury thermometers whenever possible but is also proposing flexibility by not requiring that existing equipment be modified or replaced to remove mercury thermometers already in use. The Agency anticipates that domestic and international efforts to reduce mercury usage, the environmental benefits of removing mercury from the workplace, and the economic benefits from reduced testing costs will result in generators and laboratories adopting the new methods over time. This shift toward using the new methods will result in the reduction and eventual end of mercury thermometer use in flash point testing as part of the normal process of upgrading or replacing laboratory equipment.

The Agency is interested in input from the public on whether it would be

more appropriate to remove the incorporation by reference of D 93–79, D 93–80, and D 3278–78 from SW–846 and 40 CFR 261.21 at this time. The SW–846 Test Methods program states a preference for the regulated community to use the most up-to-date version of SW–846 methods. However, to provide flexibility, both the current and proposed methods would need to be specified in the regulation. By leaving ASTM standards D 93–79, D 93–80, and D 3278–78 incorporated by reference within SW–846 Methods 1010 and 1020 and the ignitability regulation, the Agency intends to provide the regulated community the time it needs to transition between the old and new test standards. The Agency may remove ASTM standards D 93–79, D 93–80, and D 3278–78 from SW–846 Methods 1010 and 1020 and the ignitability regulation in a future update.

#### **IV. Codification of Guidance Into the Ignitability Characteristic**

##### *A. Aqueous Alcohol Exclusion*

1. Why is EPA proposing a revision to the aqueous alcohol exclusion?

As part of its effort to update the ignitability methods, the Agency reviewed the exclusion for aqueous solutions containing ignitable alcohols to determine if the exclusion should be revised. Since 1980, questions regarding the scope of the exclusion have been raised. As discussed in more detail in Section II.F. of this notice, EPA has provided clarification by interpreting the exclusion to include any alcohol or combination of alcohols (except if the alcohol has been used for its solvent properties and is one of the alcohols specified in EPA Hazardous Waste No. F003 or F005) that contains less than 24 percent alcohol by volume, even if additional non-alcoholic components are present, and at least 50 percent water by weight.

EPA has since become aware that the aqueous alcohol exclusion may inadvertently exclude certain wastes from the ignitability characteristic—aqueous liquids with small amounts of alcohol, where these wastes are ignitable due primarily to non-alcoholic components—contrary to the intent of the exclusion. For example, the exclusion may apply to an aqueous waste stream that contains a small concentration of an ignitable alcohol and a large concentration of an ignitable non-alcoholic component. This waste would be excluded from the ignitability characteristic despite potentially exhibiting the same hazards as ignitable wastes that do not fall within the scope of the exclusion.

EPA is currently unaware of existing mismanagement or damage cases resulting from this interpretation, and it may only affect a small number of (currently unknown) waste streams. The Agency solicits information on the experience of the regulated community, state authorized programs, and others in implementing this provision of the ignitability characteristic (See Section IV.A.3. in this notice).

2. What are the proposed changes to the aqueous alcohol exclusion?

Due to questions received about the alcohol exclusion under the RCRA hazardous waste ignitability characteristic, EPA wants to use this opportunity to clarify the exclusion's scope by proposing to codify the existing guidance into the regulatory text. Specifically, EPA is proposing to revise the aqueous alcohol exclusion from “other than an aqueous solution containing less than 24 percent alcohol by volume” to “other than a solution containing less than 24 percent of any alcohol or combination of alcohols (except if the alcohol has been used for its solvent properties and is one of the alcohols specified in EPA Hazardous Waste No. F003 or F005) by volume and at least 50 percent water by weight.” This proposed change removes the term “aqueous” from § 261.21(a)(1), which is currently undefined in the RCRA hazardous waste regulations, and specifies what percentage of water defines the scope of this exclusion. The Agency notes that the water content of a waste is not a method-defined parameter and more than one method or procedure may be appropriate for measuring the water content of a sample. Existing SW–846 methods for water quantification include EPA SW–846 Methods 9000 and 9001. An analyst should choose the most appropriate method for measuring water content based on the physical and chemical properties of their waste.

Codifying the guidance into the regulatory text would provide clarity and certainty for the regulated community and will remove the need for generators and laboratories or managers of waste to rely on multiple documents to understand the intended scope of the alcohol exclusion.

Today's proposed action would have no effect on 40 CFR 403.5(b)(1), which prohibits “pollutants which create a fire or explosion hazard in the POTW [publicly owned treatment work], including, but not limited to, wastestreams [sic] with a closed cup flash point of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40

CFR 261.21” with no exemption for aqueous alcohol solutions (July 24, 1990 **Federal Register**; 55 FR 30082).<sup>11</sup> Any revisions made to the aqueous alcohol exclusion in § 261.21(a)(1) from this rule would not change its inapplicability to 40 CFR 403.5(b)(1).

### 3. Solicitation of public input on other changes to the aqueous alcohol exclusion for ignitability

Because the aqueous alcohol exclusion could be interpreted to be more broadly applicable than originally intended (See Section IV.A.1. in this notice), EPA is seeking input on whether any additional revisions should be made to the aqueous alcohol exclusion in § 261.21(a)(1). The Agency is interested in the experiences of state authorized programs that manage excluded aqueous alcohols as solid waste and whether state programs have more stringent requirements. The Agency is also interested in input from waste generators, laboratories, and other members of the public who may have information regarding the specific hazards, or lack thereof, of managing waste streams pursuant to the current exclusion. This information might include: How much waste is generated and managed under the exclusion for aqueous alcohol solutions, how specific waste is currently managed, what waste-specific or industry-specific management standards or established practices for solutions of aqueous alcohol waste already exist, what waste forms are not currently excluded but may warrant exclusion due to a lack of risk to human health or the environment, what specific waste forms may currently be excluded despite presenting risks to human health or the environment, and any examples of waste mismanagement, damage, or injury resulting from waste managed under the aqueous alcohol exclusion. This information may help identify appropriate revisions to the aqueous alcohol exclusion for ignitable liquids to limit the exclusion to its original intent.

Possible revisions to the aqueous alcohol exclusion could include explicitly identifying specific waste streams in the regulation to which the exclusion would apply to remove the uncertainty regarding the current scope

<sup>11</sup> EPA evaluated whether the aqueous alcohol exclusion in § 261.21 should apply to 40 CFR 403.5(b)(1) and concluded that extending the exclusion to 40 CFR 403.5(b)(1) is not appropriate. (July 24, 1990 **Federal Register**; 55 FR at 30086). “POTW collection systems are an ideal environment for generation of flammable/ignitable atmospheres . . . allowing an exemption from the flash point prohibition for aqueous solutions containing less than 24 percent alcohol by volume would not sufficiently protect POTWs.” (ibid.)

of the exclusion and narrowing the types of alcohol that would qualify for the aqueous alcohol exclusion. Other considerations could include adding a minimum alcohol content as a requirement for excluded wastes to better target potential waste streams that flash primarily from their alcoholic components or adding to or improving the existing criteria a waste must meet to be eligible for the exclusion (e.g., raise the minimum water content for aqueous alcohol solutions) to decrease the likelihood that a liquid waste excluded from the ignitability characteristic would be able to sustain combustion or otherwise contribute to an ongoing fire. The Agency seeks information that can be used to determine appropriate revisions to the aqueous alcohol exclusion.

### B. Multiphase Testing

#### 1. Why is the Agency proposing a revision to codify sampling guidance for multiphase wastes?

The Agency has received questions in the past on sampling wastes that are multiple phases or may become multiple phases during normal management. The proposed and current test methods for ignitability contain instructions and procedures specific to that ASTM standard. The Agency is proposing to add new language to 261.21(a) to clarify that EPA’s existing sampling procedures for multiphase samples would be applicable to all liquid wastes tested under 261.21. Existing guidance from the Agency states that multiphase mixtures should be separated so that each phase is analyzed individually (discussed further below).

#### 2. Proposed Codification of Guidance for Multiphase Waste Sampling

The Agency is proposing to add a new paragraph to § 261.21(a) that clarifies how to properly test multiphase wastes containing multiple liquid(s) with or without solids for ignitability determinations. This added language would codify EPA’s long-standing sampling guidance for multiphase wastes, which are wastes that, due to differences in density (e.g., oil/water) or physical form (e.g., solid/liquid), separate into two or more phases. EPA’s long-standing sampling guidance states that for multiphase mixtures, a generator and laboratory should separate the sample into all of its different solid and/or liquid phases, to the extent practicable, and analyze each one individually in accordance with § 261.21(a) to determine whether that phase exhibits the characteristic of

ignitability. However, care should be taken to avoid loss of volatiles during separation, and it may not be possible to remove solids in all multiphase wastes. If the individual phases cannot be separated without an appreciable loss of volatiles such that the ignitability test results may be affected, then the multiphase waste should be tested for flash point as a whole.

The Agency notes that some waste mixtures may initially be one phase upon generation and later separate into two or more phases during the course of normal management. The requirement to make hazardous waste determinations upon generation and at any time during the course of management (including if phase separation occurs) is already clearly stated in 40 CFR 262.11(a). “The hazardous waste determination for each [RCRA] solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste such that the RCRA classification of the waste may change.” This policy was reaffirmed in the hazardous waste generator proposed and final rules (80 FR 57938 and 81 FR 85751).

EPA’s existing guidance on multiphase mixtures, which applies at initial generation and during the course of normal management, as applicable, in SW-846 states to break up and separate phases when possible (SW-846 Chapter 2, pp 8–9). For example, the Agency has explained that a hazardous waste determination is required for both phases of a multiphase liquid and that the RCRA sampling protocol called the COLIWASA (Composite Liquid Waste Sampler, ASTM D-5495), found in Chapter Nine of EPA’s waste testing guidance, “Test Methods for Evaluating Solid Waste (SW-846),” can be used for this purpose.<sup>12</sup> The proposed regulatory language in this notice would clarify that multiphase wastes should be separated out into its different liquid and/or solid phases, to the extent possible, before then testing each individual phase for ignitability in accordance with § 261.21.

Related to this issue, EPA notes that determining that a waste contains liquid and separating liquid from solid may be relatively straightforward through

<sup>12</sup> Letter dated November 20, 2012 from Betsy Devlin, USEPA, to Gary Jones, Printing Industries of America, available at [www.epa.gov/rcraonline](http://www.epa.gov/rcraonline) (RCRA Online Number 14834). A copy of this letter is available in the docket to today’s proposed rule.

observation, decanting, pipetting, or simple gravity filtration (*i.e.*, EPA Method 9095, Paint Filter Liquids Test or PFLT). However, confirming that a waste *does not* contain liquid might not be possible using these techniques for some wastes. In 1993, the Agency proposed Update II to SW-846, which included modified language in SW-846 to state that the pressure filtration technique specified in SW-846 Method 1311 (Toxicity Characteristic Leaching Procedure or TCLP; see Section 7.1.1) should be used to determine if a waste contains a free liquid as part of making hazardous waste characteristics determinations such as ignitability or corrosivity (August 31, 1993 **Federal Register**; 58 FR 46052). The Agency did not finalize this proposed modification due to commenters' concerns that the proposed action would discourage the use of Method 9095 (PFLT) in demonstrating that a free liquid exists. In the preamble to the final rule, EPA clarified that the pressure filtration technique should be used to definitively determine that a free liquid *did not* exist (January 13, 1995 **Federal Register**; 60 FR 3089). EPA stated,

"The definitive procedure for determining if a waste contains a liquid for the purposes of the ignitability and corrosivity characteristics is the pressure filtration technique specified in Method 1311. However, if one obtains a free liquid phase using Method 9095, then that liquid may instead be used for purposes of determining ignitability and corrosivity. However, wastes that do not yield a free liquid phase using Method 9095 should then be assessed for the presence of an ignitable or corrosive liquid using the pressure filtration technique specified in Method 1311." (60 FR 3092, January 13, 1995).

EPA also stated that it may re-propose modifying its guidance in Chapter 7 to reflect its stated position. Therefore, we are requesting comment on adding this language—which reflects EPA's position on determining free liquids—to SW-846 as guidance. Finally, with regard to separating multiphase wastes for purposes of testing, we note that Method 9095B or the pressure filtration technique in Method 1311 can be used to remove solids in multiple phase mixtures, whenever practical.

#### V. Additional Corrections to § 261.21

##### A. What are the proposed changes to the definition of ignitable compressed gas in § 261.21(a)(3)(ii)?

As part of its effort to modernize and update the RCRA ignitability characteristic regulations in § 261.21, the Agency is proposing corrections to the ignitable compressed gas definitions in § 261.21(a)(3)(ii), where EPA has

determined that particular Department of Transportation (DOT) regulations originally relied upon by EPA have subsequently changed, or certain guidance is no longer available.

First, EPA is proposing to update § 261.21(a)(3)(ii)(A) to replace outdated references to the Bureau of Explosives and DOT. The current EPA regulation at § 261.21(a)(3)(ii)(A) establishes that a waste compressed gas is ignitable under RCRA when certain flammability concentration criteria are met, as determined "using a test acceptable to the Bureau of Explosives and approved by the director of the Pipeline and Hazardous Materials Technology, U.S. Department of Transportation". However, subsequent to the EPA's original promulgation of this provision, DOT modified their regulations to require ASTM standard E 681-85 or "other equivalent method approved by the [PHMSA] Associate Administrator" as an approved test for this purpose (55 FR 52433). See 49 CFR 173.115(a). EPA also notes that the Bureau of Explosives is no longer the delegated authority from DOT to determine this testing requirement. (See communications with Bureau of Explosives in the docket to this proposed rule.) Therefore, EPA is proposing to revise § 261.21(a)(3)(ii)(A) to specify the ASTM standard E 681-85 as the approved test for determining whether any waste that is an ignitable compressed gas exhibits the RCRA ignitability characteristic, and to remove reference to the Bureau of Explosives as an approving agency for sampling and test methods. Consistent with the current DOT regulations, EPA is also proposing to correct in its own regulations the reference identifying the agency responsible for approving other tests as equivalent for this purpose, by adding the phrase "approved by the Associate Administrator, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation."

EPA is also proposing to revise § 261.21(a)(3)(ii)(B)-(D) to align with the existing DOT regulations for flammable gases. Paragraphs (B), (C) and (D) in § 261.21(a)(3)(ii) reference "Flame Projection Apparatus," "Open Drum Apparatus," and "Closed Drum Apparatus," all of which are described as methods from the Bureau of Explosives. EPA inquired with the Bureau of Explosives about the continued availability of these test methods and found that the methods were unavailable. (See correspondence with the Bureau of Explosives in the docket to this proposed rule.) In 1980, the Agency incorporated these Bureau of Explosives test methods into its

RCRA regulations to be consistent with how flammable gases were defined by DOT requirements. (See 45 FR 33108, May 19, 1980 **Federal Register**; see also Ignitability Background Document, U.S. EPA, May 2, 1980 in the docket to this proposed rule.) However, as discussed earlier, DOT subsequently updated their definition and testing requirements. Therefore, the Agency is proposing to update the definition of ignitable compressed gas within § 261.21(a)(3)(ii)(B)-(D), by removing references to Bureau of Explosives methods, and to mirror the definition and testing that DOT now requires. This change will allow generators to determine if their waste meets the definition of an ignitable compressed gas by determining if it meets the definition of a Division 2.1 flammable gas or a flammable aerosol (see 49 CFR 173.115(a) and (l)).

EPA believes that these updates are necessary to ensure that the RCRA definition reflects the current DOT regulations for evaluating ignitable compressed gases, consistent with EPA's longstanding approach to incorporate certain DOT requirements when establishing definitions (and associated test methods) that reflect routine waste management conditions for these types of wastes.

##### B. What are the proposed changes to § 261.21(a)(4)(i)(A)?

In 40 CFR part 261, EPA is amending this paragraph to read, "The material meets the definition of a Division 1.1, 1.2, or 1.3 explosive, as defined in § 261.23(a)(8), in which case it must be classed as an explosive."

Currently, § 261.21(a)(4)(i)(A) references "a Class A explosive or a Class B explosive." The terms Class A and B explosives came from the classification system for explosives used by DOT before 1991. However, DOT revised its classification system for explosives, based on the United Nations Recommendations on the Transport of Dangerous Goods, as part of a final rule issued on December 21, 1990 amending the Hazardous Materials Regulations (55 FR 52402). The new system replaced the use of explosive classes A, B, and C with the classification codes of 1.1, 1.2, 1.3, and 1.4 (49 CFR 173.53). EPA issued a direct final rule on March 18, 2010 that, in part, incorporated these changes into the RCRA hazardous waste regulations. (75 FR 12989). This direct rule amended 40 CFR 261.23(a)(8) to read, "It is a forbidden explosive as defined in 49 CFR 173.54, or is a Division 1.1, 1.2 or 1.3 explosive as defined in 49 CFR 173.50 and 173.53." (75 FR 13002). Before this revision, 40

CFR 261.23(a)(8) referenced DOT's regulations addressing Class A explosives and Class B explosives. However, as the preamble to the rule pointed out, "these cross-references are out of date with the current DOT regulations, and the referenced sections either no longer exist or no longer address these explosives. This change modifies the rule to provide the correct citations." (75 FR 12993). Section 261.21(a)(4)(i)(A) was overlooked by the 2010 EPA rulemaking, and this proposed change corrects that by updating § 261.21(a)(4)(i)(A) with the correct references.

*C. What are the proposed changes to the notes section of § 261.21?*

EPA proposes to delete the four notes at the end of 40 CFR 261.21, which are outdated or unnecessary to understanding the regulation.

EPA intends to delete Note 1 because the Bureau of Explosives will no longer be the source for the methods identified in 261.21(a)(3)(ii)(B)–(D). The current language for Note 1 states that a "description of the Bureau of Explosives' Flame Projection Apparatus, Open Drum Apparatus, Closed Drum Apparatus, and method of tests may be procured from the Bureau of Explosives."

EPA proposes to delete Notes 2 and 3. Notes 2 and 3, respectively, state that as part of a U.S. Department of Transportation (DOT) reorganization, the Office of Hazardous Materials Technology (OHMT), which was the office listed in the 1980 publication of 49 CFR 173.300 for the purposes of approving sampling and test procedures for a flammable gas, and the Research and Special Programs Administration (RSPA), which was the office listed in the 1980 publication of 49 CFR 173.151a for the purposes of determining that a material does not present a hazard in transport, ceased operations on February 20, 2005. OHMT and RSPA programs have moved to the Pipeline and Hazardous Materials Safety Administration (PHMSA) in the DOT. This historical information is no longer necessary to understanding the regulation.

EPA also proposes to delete Note 4. Note 4 was added in a 2006 EPA rulemaking to provide referential information to the change made to 40 CFR 261.21(a)(4) in the same action (71 FR 40254). Before the 2006 rule, 40 CFR 261.21(a)(4) incorporated by reference the DOT regulation that defined an oxidizer, 49 CFR 173.151. In 1990, DOT revised its regulations governing transportation of hazardous materials (55 FR 52402), including 49 CFR

173.151. However, 40 CFR 261.21(a)(4) retained the original DOT definition of an oxidizer, causing the DOT section it referenced to become irrelevant after 1990. EPA's 2006 final rule replaced the obsolete DOT reference in 40 CFR 261.21(a)(4) with the actual language from 49 CFR 173.151 as it existed at the time 40 CFR 261.21 was finalized in 1980. Note 4 states that "[t]he DOT regulatory definition of an oxidizer was contained in § 173.151 of 49 CFR, and the definition of an organic peroxide was contained in paragraph 173.151a. An organic peroxide is a type of oxidizer." EPA proposes to remove Note 4 in this rulemaking to avoid possible confusion, particularly because it can be difficult to obtain copies of the CFR from 1980.

**VI. Revision to Mercury Thermometer Requirements in the Air Sampling and Stack Emissions Methods**

*A. Why is EPA proposing revisions to the air sampling and stack emissions methods?*

Earlier in this action, EPA proposed to modernize flash point determinations for ignitable liquids by revising Methods 1010A and 1020B to adopt modern consensus-based standards that allow flexibility in temperature measurement devices (see Section III.A.). Similarly, EPA is proposing to update the SW-846 air sampling and stack emissions methods that use mercury thermometers and are method-defined parameters. These methods are Methods 0010, 0011, 0020, 0023A, and 0051. This update would provide current users of these methods the flexibility to use alternative temperature-measuring devices instead of the currently required mercury thermometers. The current users of Methods 0010, 0011, 0020, 0023A, and 0051 would be able to continue using mercury thermometers if desired. While the test methods for flash point of ignitable liquids and test methods for air sampling and stack emissions methods are unrelated in the hazard and matrix of waste they analyze, the underlying rationale and environmental benefits of providing the flexibility to use alternatives to mercury thermometers are the same. As a result, EPA is proposing these method revisions in the same action. See Section II.G. above for more information on the effects of mercury on human health and the environment.

*B. Proposed Changes to Mercury Thermometer Requirements in SW-846 Method-Defined Parameter Air Sampling and Stack Emissions Methods*

EPA has identified five SW-846 method-defined parameter test methods for air sampling and stack emissions methods that require the use of mercury thermometers: Methods 0010, 0011, 0020, 0023A, and 0051 (see Section VI.A.). These sampling methods cover emissions from stationary sources, such as hazardous waste incinerators and boilers and industrial furnaces. Many of these sampling methods are modifications of, or are similar to, EPA Method 5 of Appendix A-3 of 40 CFR 60, Determination of Particulate Matter Emissions from Stationary Sources. For Method 5, EPA proposed (77 FR 1130, Jan 9, 2012), and finalized (79 FR 11228, Feb 27, 2014), the use of alternative mercury-free thermometers if the thermometers are, at a minimum, equivalent in terms of performance or are suitably effective for the specific temperature measurement application. EPA is proposing to add similar language, where appropriate, in SW-846 Methods 0010, 0011, 0020, 0023A, and 0051. The removal of the requirement to use mercury thermometers does not change the underlying technology of the methods. Therefore, in accordance with the SW-846 methods policy statement, the method numbers and letters are not being revised due to these changes (see <https://www.epa.gov/hw-sw846/policy-statement-about-test-methods-evaluating-solid-waste-physicalchemical-methods>). The Agency anticipates that the addition of mercury thermometer alternatives to these methods (*i.e.*, the mirroring of changes made to regulatory requirements under Method 5) should result in a minimal impact to the regulated community. For example, analytical laboratories that offer these air sampling and stack emissions methods also likely offer Method 5 testing, which already allows for non-mercury thermometer usage. Labs that have non-mercury thermometers for calibrating Method 5 should recognize the benefits of reduced mercury thermometer usage while incurring no additional costs. Alternatively, laboratories may continue using mercury thermometers in the updated methods (see Section III.E.).

**VII. Incorporation by Reference**

The Methods Innovation Rule, which was finalized on June 14, 2005, revised 40 CFR 260.11 to remove the incorporation by reference of all SW-846 methods except those SW-846

methods that are also regulatory required method-defined parameters. Those methods remain incorporated by reference when used as method-defined parameters under the RCRA regulations and, thus, can only be amended through a regulatory effort.<sup>13</sup>

The Agency is proposing to incorporate by reference ASTM D 8174–18, ASTM D 8175–18, ASTM E 681–85, SW–846 Method 1010B and SW–846 Method 1020C into § 261.21 and as applicable into Appendix IX to part 261. These test methods are described in detail in Section III and Section V, above. The Agency is also proposing to incorporate by reference SW–846 Test Methods 0010, 0011, 0020, 0023A, and 0051. These test methods are updated versions of currently incorporated by reference SW–846 Methods 0010, 0011, 0020, 0023A, and 0051, as described in Section VI, above. The Agency is proposing to incorporate by reference Method 0010 into § 260.11(c)(3)(i) and Appendix IX to part 261. The Agency is proposing to incorporate by reference Method 0011 into § 260.11(c)(3)(viii) and Appendix IX to part 261. The Agency is proposing to incorporate by reference Method 0020 into § 260.11(c)(3)(ii) and Appendix IX to part 261. The Agency is proposing to incorporate by reference Method 0023A into § 260.11(c)(3)(ix) Appendix IX to part 261, § 266.104(e)(1), and Appendix IX to part 266. The Agency is proposing to incorporate by reference Method 0051 into § 260.11(c)(3)(xiii), Appendix IX to part 261, § 266.107(f), and Appendix IX to part 266. The Agency is also proposing to incorporate by reference Method 0011 into § 260.11(c)(3)(viii) and Appendix IX to part 266. The ASTM standards proposed for incorporation by reference are available for purchase from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, [www.astm.org](http://www.astm.org), 877–909–2786. To obtain ASTM E 681–85, call 877–909–2786. The SW–846 Test Methods proposed for incorporation by reference are published in the test methods compendium known as “Test Methods for Evaluating Solid Waste, Physical/Chemical Methods,” EPA Publication SW–846, Third Edition, available at <https://www.epa.gov/hw-sw846>.

<sup>13</sup> It is important to note that while a method listed in § 260.11 is a method-defined parameter, that method also may be used for non-mandatory purposes. For example, the Pensky-Martens method described in Method 1010A could also be used as part of quality control to test a product for purity, which is unrelated to § 261.21 and, otherwise, not required under RCRA. In this case, the method would not be a method-defined parameter. In order to be a method-defined parameter, a method must be part of a regulatory requirement under RCRA.

## VIII. State Authorization

### A. Applicability of Proposed Rule in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified states to administer and enforce the RCRA hazardous waste program within the state. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized states have primary enforcement responsibility. The standards and requirements for state authorization are found at 40 CFR part 271. Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that state. The federal requirements no longer applied in the authorized state, and EPA could not issue permits for any facilities in that state, since only the state was authorized to issue RCRA permits. When EPA promulgated new, more stringent federal requirements for these pre-HSWA regulations, the state was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized state, until the state adopted the federal requirements as state law. In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. EPA is directed by the statute to implement these requirements and prohibitions in authorized states, including the issuance of permits, until the state is granted authorization to do so. While states must still adopt HSWA related provisions as state law to retain final authorization, EPA implements the HSWA provisions in authorized states until the states do so.

Authorized states are required to modify their programs only when EPA enacts federal requirements that are more stringent or broader in scope than existing federal requirements.<sup>14</sup> RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see also 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-

<sup>14</sup> EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

HSWA, that are considered less stringent than previous federal regulations.

### B. Effect on State Authorization

Today’s notice proposes regulations that, if finalized, would not be promulgated under the authority of HSWA. Thus, the standards, if finalized, would be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs. This is a result of section 3009 of RCRA, which allows states to impose more stringent regulations than the federal program.

The proposed revisions to several test methods are considered to be neither more nor less stringent than the existing test methods. Thus, authorized states may, but are not required to, adopt these changes.

## IX. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at <http://www.epa.gov/laws-regulations/laws-and-executive-orders>.

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

This action is not a significant regulatory action because it does not have a significant economic impact nor does it raise novel legal or policy issues. The Office of Management and Budget (OMB) waived review.

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

This action is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in EPA’s *Regulatory Impact Analysis of the Modernization of Ignitable Liquid Determination Rule*, which is in the docket.

### C. Paperwork Reduction Act (PRA)

The use of the proposed methods or the existing methods impose the same information collection burden as the existing regulation. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB

control numbers 2050–0053 and 2050–0073.

#### D. Regulatory Flexibility Act (RFA)

I certify that this proposed action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the *Regulatory Impact Analysis of the Modernization of Ignitable Liquid Determinations Rule* found in the docket for this proposal, EPA does not expect the rule to result in an adverse impact to a significant number of small entities. For commercial labs, the analysis presented in Chapter 3 indicates either no change in costs or a cost savings, due to the flexibility afforded by the rule. Therefore, out of the 128 firms defined as small under the Small Business Administration size standards, no firms have costs greater than one percent of annual revenues. EPA has therefore concluded that this proposed action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

#### E. Unfunded Mandates Reform Act (UMRA)

As documented in the *Regulatory Impact Analysis of the Modernization of Ignitable Liquid Determinations Rule* found in the docket for this proposal, this proposed action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

#### F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This proposed action does not have tribal implications as specified in Executive Order 13175. Because the proposed rule is expected to result in minimal costs and possibly net cost

savings, EPA does not expect that it would result in any adverse impacts on tribal entities. Thus, Executive Order 13175 does not apply to this rule.

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

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

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

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

#### J. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. The EPA proposes to use ASTM D 8175–18 and ASTM D 8174–18. These test methods were adopted by ASTM in March 2018. These standards are available for purchase from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959. EPA worked with ASTM to specifically develop these consensus-based standards to better suit waste testing by modifying existing ASTM standards. EPA worked with a member of the ASTM D02.08 Subcommittee (who also represents Stanhope-Seta) to modify existing ASTM methods D 93–16 and D 3828–16a, which were developed by the ASTM D02.08 Subcommittee. These new draft methods were then submitted to ASTM’s review process and were approved by the ASTM D34 Committee to become new ASTM methods.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This proposed rule would only modernize testing and codify guidance

for the characterization of ignitable hazardous waste, it would not affect how such waste is disposed of. EPA therefore does not expect it to result in any adverse environmental justice impacts.

#### List of Subjects

##### 40 CFR Part 260

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Incorporation by reference, Reporting and recordkeeping requirements.

##### 40 CFR Part 261

Environmental protection, Hazardous waste, Incorporation by reference, Recycling, Reporting and recordkeeping requirements.

##### 40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Incorporation by reference, Recycling, Reporting and recordkeeping requirements.

Dated: March 21, 2019.

**Andrew R. Wheeler,**  
Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR parts 260 and 261 as follows:

#### PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

■ 2. Amend § 260.11 by:

■ a. Adding new paragraphs (b)(11) through (13); and

■ b. Revising paragraphs (c)(3)(i), (ii), (viii), (ix), (xiii), (xvii), and (xviii).

The additions and revisions read as follows:

##### § 260.11 Incorporation by reference.

\* \* \* \* \*

(b) \* \* \*

\* \* \* \* \*

(11) ASTM D 8175–18 “Test Method for Finite Flash Point Determination of Liquid Wastes by Pensky-Martens Closed Cup Tester.” IBR approved for § 261.21.

(12) ASTM D 8174–18 “Test Method for Finite Flash Point Determination of Liquid Wastes by Small Scale Closed Cup Tester.” IBR approved for § 261.21.

(13) ASTM E 681–85 “Standard Test Method for Concentration Limits of Flammability of Chemicals (Vapors and gases).” IBR approved for § 261.21.

(c) \* \* \*

(3) \* \* \*

(i) Method 0010, dated [TBD] and in the Basic Manual, IBR approved for appendix IX to part 261.

(ii) Method 0020, dated [TBD] and in the Basic Manual, IBR approved for appendix IX to part 261.

\* \* \* \* \*

(viii) Method 0011, dated [TBD] and in Update III, IBR approved for appendix IX to part 261 and appendix IX to part 266.

(ix) Method 0023A, dated [TBD] and in Update III, IBR approved for appendix IX to part 261, § 266.104, and appendix IX to part 266, .

\* \* \* \* \*

(xiii) Method 0051, dated [TBD] and in Update III, IBR approved for appendix IX to part 261, § 266.107, and appendix IX to part 266,

\* \* \* \* \*

(xvii) Method 1010B, dated December 2018 and in Update VII, IBR approved for § 261.21 and appendix IX to part 261.

(xviii) Method 1020C, dated December 2018 and in Update VII, IBR approved for § 261.21 and appendix IX to part 261.

\* \* \* \* \*

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

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

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 4. Amend § 261.21 by:

■ a. Revising paragraphs (a)(1), (3)(ii), and (4)(i)(A) adding paragraph (a)(5); and

■ b. Removing Notes 1, 2, 3, and 4 to read as follows:

**§ 261.21 Characteristic of ignitability.**

(a) \* \* \*

(1) It is a liquid, other than a solution containing less than 24 percent of any alcohol or combination of alcohols (except if the alcohol has been used for its solvent properties and is one of the alcohols specified in EPA Hazardous Waste No. F003 or F005 in 40 CFR 261.31) by volume and at least 50 percent water by weight, that has a flash point less than 60 °C (140 °F), as determined by using one of the following ASTM standards: ASTM D 93–79, D 93–80, D 3278–78, D 8174–18 or D 8175–18 as specified in SW–846 Test Methods 1010B or 1020C (incorporated by reference, see § 260.11 of this subchapter).

\* \* \* \* \*

(3) \* \* \*

(ii) A compressed gas shall be characterized as ignitable if any one of the following occurs:

(A) Either a mixture of 13 percent or less (by volume) with air forms a flammable mixture or the flammable range with air is wider than 12 percent regardless of the lower limit. These limits shall be determined at atmospheric temperature and pressure. The method of sampling and test procedure shall be the ASTM E 681–85 (incorporated by reference, see § 260.11 of this subchapter), or other equivalent methods approved by the Associate Administrator, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation.

(B) It is determined to be flammable or extremely flammable using 49 CFR 173.115(l).

(4) \* \* \*

(i) \* \* \*

(A) The material meets the definition of a Division 1.1, 1.2, or 1.3 explosive, as defined in § 261.23(a)(8), in which case it must be classed as an explosive,

\* \* \* \* \*

(5) It is a multiphase mixture, where any liquid phase has the flash point described in paragraph (a)(1) of this section, or any non-liquid phase has the properties described in paragraph (a)(2) of this section.

\* \* \* \* \*

5. Amend Tables 1 and 2 of Appendix IX to Part 261 by removing the text “1010A” and adding “1010B” in its place, wherever it appears (56 occurrences); and removing the text “1020B” and adding “1020C” in its place, wherever it appears (56 occurrences).

[FR Doc. 2019–05878 Filed 4–1–19; 8:45 am]

**BILLING CODE 6560–50–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 600**

**[CMS–2407–PN]**

**RIN 0938–ZB42**

**Basic Health Program; Federal Funding Methodology for Program Years 2019 and 2020**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed methodology.

**SUMMARY:** This document proposes the methodology and data sources necessary

to determine federal payment amounts to be made in program years 2019 and 2020 to states that elect to establish a Basic Health Program under the Patient Protection and Affordable Care Act to offer health benefits coverage to low-income individuals otherwise eligible to purchase coverage through Affordable Insurance Exchanges. Prior to the final notice being published, Basic Health Program (BHP) payments will be made using the methodology described in the Final Administrative Order published on August 24, 2018. Payments for 2019 will be conformed to the finalized 2019 payment methodology through reconciliation.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 2, 2019.

**ADDRESSES:** In commenting, refer to file code CMS–2407–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2407–PN, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2407–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Christopher Truffer, (410) 786–1264; or Cassandra Lagorio, (410) 786–4554.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the

comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

## I. Background

### A. Overview of the Basic Health Program

Section 1331 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively referred to as the Affordable Care Act) provides states with an option to establish a Basic Health Program (BHP). In the states that elect to operate a BHP, the BHP will make affordable health benefits coverage available for individuals under age 65 with household incomes between 133 percent and 200 percent of the federal poverty level (FPL) who are not otherwise eligible for Medicaid, the Children’s Health Insurance Program (CHIP), or affordable employer-sponsored coverage, or for individuals whose income is below these levels but are lawfully present non-citizens ineligible for Medicaid. (For those states that have expanded Medicaid coverage under section 1902(a)(10)(A)(i)(VIII) of the Social Security Act (the Act), the lower income threshold for BHP eligibility is effectively 138 percent due to the application of a required 5 percent income disregard in determining the upper limits of Medicaid income eligibility (section 1902(e)(14)(I) of the Act)).

A BHP provides another option for states in providing affordable health benefits to individuals with incomes in the ranges described above. States may find a BHP a useful option for several reasons, including the ability to potentially coordinate standard health plans in the BHP with their Medicaid managed care plans, or to potentially reduce the costs to individuals by lowering premiums or cost-sharing requirements.

Federal funding for a BHP under section 1331(d)(3)(A) of the Affordable Care Act is based on the amount of premium tax credit (PTC) and cost-sharing reductions (CSRs) that would have been provided for the fiscal year to eligible individuals enrolled in BHP standard health plans in the state if such eligible individuals were allowed to enroll in a qualified health plan (QHP) through Affordable Insurance Exchanges (“Exchanges”). These funds are paid to trusts established by the states and

dedicated to the BHP, and the states then administer the payments to standard health plans within the BHP.

In the March 12, 2014 **Federal Register** (79 FR 14112), we published a final rule entitled the “Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity” (hereinafter referred to as the BHP final rule) implementing section 1331 of the Affordable Care Act, which governs the establishment of BHPs. The BHP final rule establishes the standards for state and federal administration of BHPs, including provisions regarding eligibility and enrollment, benefits, cost-sharing requirements and oversight activities. While the BHP final rule codifies the overall statutory requirements and basic procedural framework for the funding methodology, it does not contain the specific information necessary to determine federal payments. We anticipated that the methodology would be based on data and assumptions that would reflect ongoing operations and experience of BHPs, as well as the operation of the Exchanges. For this reason, the BHP final rule indicated that the development and publication of the funding methodology, including any data sources, would be addressed in a separate annual BHP Payment Notice.

In the BHP final rule, we specified that the BHP Payment Notice process would include the annual publication of both a proposed and final BHP Payment Notice. The proposed BHP Payment Notice would be published in the **Federal Register** each October, and would describe the proposed funding methodology for the upcoming BHP program year,<sup>1</sup> including how the Secretary considered the factors specified in section 1331(d)(3) of the Affordable Care Act, along with the proposed data sources used to determine the federal BHP payment rates. The final BHP Payment Notice would be published in the **Federal Register** in February, and would include the final BHP funding methodology, as well as the federal BHP payment rates for the next BHP program year. For example, payment rates published in February 2019 would apply to BHP program year 2020, beginning in January 2020. As discussed in section II.C of this

<sup>1</sup> BHP program years span from January to December.

notice, and as referenced in 42 CFR 600.610(b)(2), state data needed to calculate the federal BHP payment rates for the final BHP Payment Notice must be submitted to CMS.

As described in the BHP final rule, once the final methodology has been published, we will only make modifications to the BHP funding methodology on a prospective basis with limited exceptions. The BHP final rule provided that retrospective adjustments to the state’s BHP payment amount may occur to the extent that the prevailing BHP funding methodology for a given program year permits adjustments to a state’s federal BHP payment amount due to insufficient data for prospective determination of the relevant factors specified in the payment notice. Additional adjustments could be made to the payment rates to correct errors in applying the methodology (such as mathematical errors).

Under section 1331(d)(3)(ii) of the Affordable Care Act, the funding methodology and payment rates are expressed as an amount per eligible individual enrolled in a BHP standard health plan (BHP enrollee) for each month of enrollment. These payment rates may vary based on categories or classes of enrollees. Actual payment to a state would depend on the actual enrollment of individuals found eligible in accordance with a state’s certified BHP Blueprint eligibility and verification methodologies in coverage through the state BHP. A state that is approved to implement a BHP must provide data showing quarterly enrollment of eligible individuals in the various federal BHP payment rate cells. Such data should include the following:

- Personal identifier;
- Date of birth;
- County of residence;
- Indian status;
- Family size;
- Household income;
- Number of persons in household enrolled in BHP;
- Family identifier;
- Months of coverage;
- Plan information; and
- Any other data required by CMS to properly calculate the payment.

### B. 2018 Funding Methodology and Changes in Final Administrative Order

In the February 29, 2016 **Federal Register** (81 FR 10091), we published the final notice entitled “Basic Health Program; Federal Funding Methodology for Program Years 2017 and 2018” (hereinafter referred to as the February 2016 payment notice) that sets forth the methodology that would be used to

calculate the federal BHP payments for the 2017 and 2018 program years. Updated factors for the program year 2018 federal BHP payments were provided in the CMCS Informational Bulletin, “Basic Health Program; Federal Funding Methodology for Program Year 2018” on May 17, 2017.

On October 11, 2017, the Attorney General of the United States provided the Department of Health and Human Services and the Department of Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324, from which the Departments had historically drawn funds to make CSR payments, cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—the Department of Health and Human Services directed us to discontinue CSR payments to issuers until Congress provides for an appropriation. In the absence of a Congressional appropriation for federal funding for CSRs, we cannot provide states with a federal payment attributable to CSRs that BHP enrollees would have received had they been enrolled in a QHP through an Exchange.

Starting with the payment for the first quarter (Q1) of 2018 (which began on January 1, 2018), we stopped paying the CSR component of the quarterly BHP payments to New York and Minnesota (the states), the only states operating a BHP in 2018. The states then sued the Secretary for declaratory and injunctive relief in the United States District Court for the Southern District of New York. *See State of New York, et al, v. U.S. Department of Health and Human Services*, 18-cv-00683 (S.D.N.Y. filed Jan. 26, 2018). On May 2, 2018, the parties filed a stipulation requesting a 60-day stay of the litigation so that HHS could issue an administrative order revising the 2018 BHP payment methodology. As a result of the stipulation, the court dismissed the BHP litigation, although it retained jurisdiction to enforce the stipulation and re-open the docket. On July 6, 2018, we issued a Draft Administrative Order on which New York and Minnesota had an opportunity to comment. The states each submitted comments on August 6, 2018. We considered the states’ comments and issued a Final Administrative Order on August 24, 2018 setting forth the payment methodology that would only apply to the 2018 BHP benefit year. The payment methodology proposed in this notice would apply the methodology described in the Final Administrative Order with one additional adjustment to account for

the impact of individuals selecting different metal-tier level plans in the Exchange. The payment methodology proposed in this notice would apply to program years 2019 and 2020.

We will be making future BHP payments for program year 2019 using the methodology described in the Final Administrative Order published on August 24, 2018 until a final methodology for 2019 and 2020 is published. If necessary, any payments for 2019 will be conformed to the finalized 2019 payment methodology through reconciliation.

## II. Provisions of the Proposed Notice

### A. Overview of the Funding Methodology and Calculation of the Payment Amount

Section 1331(d)(3) of the Affordable Care Act directs the Secretary to consider several factors when determining the federal BHP payment amount, which, as specified in the statute, must equal 95 percent of the value of the PTC and CSRs that BHP enrollees would have been provided had they enrolled in a QHP through an Exchange. Thus, the BHP funding methodology is designed to calculate the PTC and CSRs as consistently as possible and in general alignment with the methodology used by Exchanges to calculate the advance payments of the PTC and CSRs, and by the Internal Revenue Service (IRS) to calculate final PTCs. In general, we have relied on values for factors in the payment methodology specified in statute or other regulations as available, and have developed values for other factors not otherwise specified in statute, or previously calculated in other regulations, to simulate the values of the PTC and CSRs that BHP enrollees would have received if they had enrolled in QHPs offered through an Exchange. In accordance with section 1331(d)(3)(A)(iii) of the Affordable Care Act, the final funding methodology must be certified by the Chief Actuary of CMS, in consultation with the Office of Tax Analysis (OTA) of the Department of the Treasury, as having met the requirements of section 1331(d)(3)(A)(ii) of the Affordable Care Act.

Section 1331(d)(3)(A)(ii) of the Affordable Care Act specifies that the payment determination shall take into account all relevant factors necessary to determine the value of the PTCs and CSRs that would have been provided to eligible individuals, including but not limited to, the age and income of the enrollee, whether the enrollment is for self-only or family coverage, geographic

differences in average spending for health care across rating areas, the health status of the enrollee for purposes of determining risk adjustment payments and reinsurance payments that would have been made if the enrollee had enrolled in a QHP through an Exchange, and whether any reconciliation of PTC and CSR would have occurred if the enrollee had been so enrolled. Under the payment methodologies for 2015 (79 FR 13887, published on March 12, 2014), for 2016 (80 FR 9636, published on February 24, 2015), and for 2017 and 2018 (81 FR 10091, published on February 29, 2016), the total federal BHP payment amount has been calculated using multiple rate cells in each state. Each rate cell represents a unique combination of age range, geographic area, coverage category (for example, self-only or two-adult coverage through the BHP), household size, and income range as a percentage of FPL, and there is a distinct rate cell for individuals in each coverage category within a particular age range who reside in a specific geographic area and are in households of the same size and income range. The BHP payment rates developed also are consistent with the state’s rules on age rating. Thus, in the case of a state that does not use age as a rating factor on an Exchange, the BHP payment rates would not vary by age.

Under the methodology in the Final Administrative Order, the rate for each rate cell is calculated in two parts. The first part is equal to 95 percent of the estimated PTC that would have been paid if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. The second part is equal to 95 percent of the estimated CSR payment that would have been made if a BHP enrollee in that rate cell had instead enrolled in a QHP in an Exchange. These 2 parts are added together and the total rate for that rate cell would be equal to the sum of the PTC and CSR rates. As noted in the Final Administrative Order, we will assign a value of zero to the CSR portion of the BHP payment rate calculation, because there is presently no available appropriation from which we can make the CSR portion of any BHP Payment.

We propose that Equation (1) would be used to calculate the estimated PTC for eligible individuals enrolled in the BHP in each rate cell. We note that throughout this payment notice, when we refer to enrollees and enrollment data, we mean data regarding individuals who are enrolled in the BHP who have been found eligible for the BHP using the eligibility and verification requirements that are

applicable in the state's most recent certified Blueprint. By applying the equations separately to rate cells based on age, income and other factors, we would effectively take those factors into account in the calculation. In addition, the equations would reflect the estimated experience of individuals in each rate cell if enrolled in coverage through an Exchange, taking into account additional relevant variables. Each of the variables in the equations is defined in this section, and further detail is provided later in this section of this payment notice. In addition, we describe how we propose to calculate the adjusted reference premium (ARP) (described later in this section of the payment notice) that is used in Equation (1). This is defined in Equation (2a) and Equation (2b).

*Equation 1: Estimated PTC by Rate Cell*

We propose that the estimated PTC, on a per enrollee basis, would continue to be calculated for each rate cell for each state based on age range,

geographic area, coverage category, household size, and income range. The PTC portion of the rate would be calculated in a manner consistent with the methodology used to calculate the PTC for persons enrolled in a QHP, with 5 adjustments. First, the PTC portion of the rate for each rate cell would represent the mean, or average, expected PTC that all persons in the rate cell would receive, rather than being calculated for each individual enrollee. Second, the reference premium (RP) (described in more detail later in the section) used to calculate the PTC would be adjusted for the BHP population health status, and in the case of a state that elects to use 2018 premiums for the basis of the BHP federal payment, for the projected change in the premium from 2018 to 2019, to which the rates announced in the final payment methodology would apply. These adjustments are described in Equation (2a) and Equation (2b). Third, the PTC would be adjusted prospectively to reflect the mean, or

average, net expected impact of income reconciliation on the combination of all persons enrolled in the BHP; this adjustment, as described in section II.D.5 of this notice, would account for the impact on the PTC that would have occurred had such reconciliation been performed. Fourth, the PTC would be adjusted to account for the estimated impacts of plan selection; this adjustment, the metal tier selection factor (MTSF), would reflect the effect on the average PTC of individuals choosing different metal-tier levels of QHPs. Finally, the rate is multiplied by 95 percent, consistent with section 1331(d)(3)(A)(i) of the Affordable Care Act. We note that in the situation where the average income contribution of an enrollee would exceed the ARP, we would calculate the PTC to be equal to 0 and would not allow the value of the PTC to be negative.

We propose using Equation (1) to calculate the PTC rate, consistent with the methodology described above:

$$\text{Equation (1): } PTC_{a,g,c,h,i} = \left[ ARP_{a,g,c} - \frac{\sum_j I_{h,i,j} \times PTCF_{h,i,j}}{n} \right] \times IRF \times MTSF \times 95\%$$

$PTC_{a,g,c,h,i}$  = Premium tax credit portion of BHP payment rate  
 $a$  = Age range  
 $g$  = Geographic area  
 $c$  = Coverage status (self-only or applicable category of family coverage) obtained through BHP  
 $h$  = Household size  
 $i$  = Income range (as percentage of FPL)  
 $ARP_{a,g,c}$  = Adjusted reference premium  
 $I_{h,i,j}$  = Income (in dollars per month) at each 1 percentage-point increment of FPL  
 $j$  =  $j^{th}$  percentage-point increment FPL  
 $n$  = Number of income increments used to calculate the mean PTC  
 $PTCF_{h,i,j}$  = Premium Tax Credit Formula percentage  
 $IRF$  = Income reconciliation factor  
 $MTSF$  = Metal-tier selection factor

*Equation 2a and Equation 2b: Adjusted Reference Premium (ARP) Variable (used in Equation 1)*

As part of the calculations for the PTC component, we propose to continue to calculate the value of the ARP as described below. Consistent with the existing approach, we are proposing to allow states to choose between using the actual current year premiums or the prior year's premiums multiplied by the premium trend factor (PTF) (as described in section II.F. of this notice). Below we describe how we would continue to calculate the ARP under each option.

In the case of a state that elected to use the RP based on the current program year (for example, 2019 premiums for

the 2019 program year), we propose to calculate the value of the ARP as specified in Equation (2a). The ARP would be equal to the RP, which would be based on the second lowest cost silver plan premium in the applicable program year, multiplied by the BHP population health factor (PHF) (described in section II.D of this notice), which would reflect the projected impact that enrolling BHP-eligible individuals in QHPs through an Exchange would have had on the average QHP premium, and multiplied by the premium adjustment factor (PAF) (described in section II.D of this notice), which would account for the change in silver-level premiums due to the discontinuance of CSR payments.

$$\text{Equation (2a): } ARP_{a,g,c} = RP_{a,g,c} \times PHF \times PAF$$

$ARP_{a,g,c}$  = Adjusted reference premium  
 $a$  = Age range  
 $g$  = Geographic area  
 $c$  = Coverage status (self-only or applicable category of family coverage) obtained through BHP  
 $RP_{a,g,c}$  = Reference premium  
 $PHF$  = Population health factor  
 $PAF$  = Premium adjustment factor

In the case of a state that elected to use the RP based on the prior program year (for example, 2018 premiums for the 2019 program year, as described in more detail in section II.F of this notice), we propose to calculate the value of the ARP as specified in Equation (2b). The ARP would be equal to the RP, which would be based on the second lowest cost silver plan premium

in 2018, multiplied by the BHP PHF (described in section II.D of this notice), which would reflect the projected impact that enrolling BHP-eligible individuals in QHPs on an Exchange would have had on the average QHP premium, multiplied by the PAF (described in section II.D of this notice), which would account for the change in silver-level premiums due to the

discontinuance of CSR payments, and multiplied by the PTF (described in section II.E of this notice), which would

reflect the projected change in the premium level between 2018 and 2019.

$$\text{Equation (2b): } ARP_{a,g,c} = RP_{a,g,c} \times PHF \times PAF \times PTF$$

$ARP_{a,g,c}$  = Adjusted reference premium  
 $a$  = Age range  
 $g$  = Geographic area  
 $c$  = Coverage status (self-only or applicable category of family coverage) obtained through BHP  
 $RP_{a,g,c}$  = Reference premium

$PHF$  = Population health factor  
 $PAF$  = Premium adjustment factor  
 $PTF$  = Premium trend factor

*Equation 3: Determination of Total Monthly Payment for BHP Enrollees in Each Rate Cell*

$$\text{Equation (3): } PMT = \sum [(PTC_{a,g,c,h,i} + CSR_{a,g,c,h,i}) \times E_{a,g,c,h,i}]$$

(In this equation, we assign a value of zero to the CSR part of the BHP payment rate calculation ( $CSR_{a,g,c,h,i}$ ) because there is presently no available appropriation from which we can make the CSR portion of any BHP payment. In the event that an appropriation for CSRs for 2019 or 2020 is made, we would determine whether to modify the CSR part of the BHP payment rate calculation ( $CSR_{a,g,c,h,i}$ ) or include the PAF in the payment methodology.)

$PMT$  = Total monthly BHP payment  
 $PTC_{a,g,c,h,i}$  = Premium tax credit portion of BHP payment rate  
 $CSR_{a,g,c,h,i}$  = Cost-sharing reduction portion of BHP payment rate  
 $E_{a,g,c,h,i}$  = Number of BHP enrollees  
 $a$  = Age range  
 $g$  = Geographic area  
 $c$  = Coverage status (self-only or applicable category of family coverage) obtained through BHP  
 $h$  = Household size  
 $i$  = Income range (as percentage of FPL)

#### B. Federal BHP Payment Rate Cells

Consistent with the previous payment methodologies, we propose that a state implementing a BHP provide us an estimate of the number of BHP enrollees it projects will enroll in the upcoming BHP program quarter, by applicable rate cell, prior to the first quarter and each subsequent quarter of program operations until actual enrollment data is available. Upon our approval of such estimates as reasonable, they would be used to calculate the prospective payment for the first and subsequent quarters of program operation until the state has provided us actual enrollment data. These data would be required to calculate the final BHP payment amount, and make any necessary reconciliation adjustments to the prior quarters' prospective payment amounts due to differences between projected

and actual enrollment. Subsequent quarterly deposits to the state's trust fund would be based on the most recent actual enrollment data submitted to us. Actual enrollment data must be based on individuals enrolled for the quarter submitted who the state found eligible and whose eligibility was verified using eligibility and verification requirements as agreed to by the state in its applicable BHP Blueprint for the quarter that enrollment data is submitted. Procedures will ensure that federal payments to a state reflect actual BHP enrollment during a year, within each applicable category, and prospectively determined federal payment rates for each category of BHP enrollment, with such categories defined in terms of age range, geographic area, coverage status, household size, and income range, as explained above.

We propose requiring the use of certain rate cells as part of the proposed methodology. For each state, we propose using rate cells that separate the BHP population into separate cells based on the five factors described as follows:

*Factor 1—Age:* We propose to continue separating enrollees into rate cells by age, using the following unchanged age ranges that capture the widest variations in premiums under HHS's Default Age Curve:<sup>2</sup>

<sup>2</sup> This curve is used to implement the Affordable Care Act's 3:1 limit on age-rating in states that do not create an alternative rate structure to comply with that limit. The curve applies to all individual market plans, both within and outside the Exchange. The age bands capture the principal allowed age-based variations in premiums as permitted by this curve. The default age curve was updated for 2018 to include different age rating factors between children 0–14 and for persons at each age between 15 and 20. More information is available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Downloads/StateSpecAgeCrv053117.pdf>. Both

In general, the rate for each rate cell would be multiplied by the number of BHP enrollees in that cell (that is, the number of enrollees that meet the criteria for each rate cell) to calculate the total monthly BHP payment. This calculation is shown in Equation (3).

- Ages 0–20.
- Ages 21–34.
- Ages 35–44.
- Ages 45–54.
- Ages 55–64.

*Factor 2—Geographic area:* For each state, we propose separating enrollees into rate cells by geographic areas within which a single RP is charged by QHPs offered through the state's Exchange. Multiple, non-contiguous geographic areas would be incorporated within a single cell, so long as those areas share a common RP.<sup>3</sup> This provision would also be unchanged from the current method.

*Factor 3—Coverage status:* We propose to continue separating enrollees into rate cells by coverage status, reflecting whether an individual is enrolled in self-only coverage or persons are enrolled in family coverage through the BHP, as provided in section 1331(d)(3)(A)(ii) of the Affordable Care Act. Among recipients of family coverage through the BHP, separate rate cells, as explained below, would apply

children and adults under age 21 are charged the same premium. For adults age 21–64, the age bands in this notice divide the total age-based premium variation into the three most equally-sized ranges (defining size by the ratio between the highest and lowest premiums within the band) that are consistent with the age-bands used for risk-adjustment purposes in the HHS-Developed Risk Adjustment Model. For such age bands, see Table 5, "Age-Sex Variables," in HHS-Developed Risk Adjustment Model Algorithm Software, June 2, 2014, <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ra-tables-03-27-2014.xlsx>.

<sup>3</sup> For example, a cell within a particular state might refer to "County Group 1," "County Group 2," etc., and a table for the state would list all the counties included in each such group. These geographic areas are consistent with the geographic areas established under the 2014 Market Reform Rules. They also reflect the service area requirements applicable to QHPs, as described in 45 CFR 155.1055, except that service areas smaller than counties are addressed as explained below.

based on whether such coverage involves two adults alone or whether it involves children.

*Factor 4—Household size:* We propose to continue the current methods for separating enrollees into rate cells by household size that states use to determine BHP enrollees' household income as a percentage of the FPL under § 600.320 (Administration, eligibility, essential health benefits, performance standards, service delivery requirements, premium and cost-sharing, allotments, and reconciliation; Determination of eligibility for and enrollment in a standard health plan). We are proposing to require separate rate cells for several specific household sizes. For each additional member above the largest specified size, we propose to publish instructions for how we would develop additional rate cells and calculate an appropriate payment rate based on data for the rate cell with the closest specified household size. We propose to publish separate rate cells for household sizes of 1 through 10.

*Factor 5—Household Income:* For households of each applicable size, we propose to continue the current methods for creating separate rate cells by income range, as a percentage of FPL. The PTC that a person would receive if enrolled in a QHP through an Exchange varies by household income, both in level and as a ratio to the FPL. Thus, we propose that separate rate cells would be used to calculate federal BHP payment rates to reflect different bands of income measured as a percentage of FPL. We propose using the following income ranges, measured as a ratio to the FPL:

- 0 to 50 percent of the FPL.
- 51 to 100 percent of the FPL.
- 101 to 138 percent of the FPL.<sup>4</sup>
- 139 to 150 percent of the FPL.
- 151 to 175 percent of the FPL.
- 176 to 200 percent of the FPL.

These rate cells would only be used to calculate the federal BHP payment amount. A state implementing a BHP would not be required to use these rate cells or any of the factors in these rate cells as part of the state payment to the standard health plans participating in the BHP or to help define BHP enrollees' covered benefits, premium costs, or out-of-pocket cost-sharing levels.

We propose using averages to define federal payment rates, both for income ranges and age ranges, rather than varying such rates to correspond to each

individual BHP enrollee's age and income level. We believe that the proposed approach will increase the administrative feasibility of making federal BHP payments and reduce the likelihood of inadvertently erroneous payments resulting from highly complex methodologies. We believe that this approach should not significantly change federal payment amounts, since within applicable ranges, the BHP-eligible population is distributed relatively evenly.

The number of factors contributing to rate cells, when combined, can result in over 350,000 rate cells which can increase the complexity when generating quarterly payment amounts. In future years, and in the interest of administrative simplification, we will consider whether to combine or eliminate certain rate cells, once we are certain that the effect on payment would be insignificant.

### *C. Sources and State Data Considerations*

To the extent possible, we intend to continue to use data submitted to the federal government by QHP issuers seeking to offer coverage through the Exchange in the relevant BHP state to perform the calculations that determine federal BHP payment cell rates. We propose that the current methodology would not change, but we also propose clarifications regarding the submission of state data in this section.

States operating a State-based Exchange in the individual market, however, must provide certain data, including premiums for second lowest cost silver plans, by geographic area, for CMS to calculate the federal BHP payment rates in those states. We propose that a State-based Exchange interested in obtaining the applicable federal BHP payment rates for its state must submit such data accurately, completely, and as specified by CMS, by no later than 30 days after the publication of the final notice for CMS to calculate the applicable rates for 2019, and by no later than October 15, 2019, for CMS to calculate the applicable rates for 2020. If additional state data (that is, in addition to the second lowest cost silver plan premium data) are needed to determine the federal BHP payment rate, such data must be submitted in a timely manner, and in a format specified by us to support the development and timely release of annual BHP payment notices. The specifications for data collection to support the development of BHP payment rates will be published in CMS guidance and will be available at <http://www.medicaid.gov/Federal-Policy-Guidance/Federal-Policy-Guidance.html>.

### *Guidance/Federal-Policy-Guidance.html.*

States must submit enrollment data to us on a quarterly basis and should be technologically prepared to begin submitting data at the start of their BHP, starting with the beginning of the first program year. (This differs from the enrollment estimates used to calculate the initial BHP payment, which states would generally be submit to CMS 60 days before the start of the first quarter of the program start date.) This requirement is necessary for us to implement the payment methodology that is tied to a quarterly reconciliation based on actual enrollment data.

We propose to continue the policy adopted in the February 2016 payment notice that in states that have BHP enrollees who do not file federal tax returns (non-filers), the state must develop a methodology which they must submit to us at the time of their Blueprint submission to determine the enrollees' household income and household size consistently with Marketplace requirements. We reserve the right to approve or disapprove the state's methodology to determine household income and household size for non-filers if the household composition and/or household income resulting from application of the methodology are different than what typically would be expected to result if the individual or head of household in the family were to file a tax return.

In addition, as the federal payments are determined quarterly and the enrollment data is required to be submitted by the states to us quarterly, we propose that the quarterly payment would be based on the characteristics of the enrollee at the beginning of the quarter (or their first month of enrollment in the BHP in each quarter). Thus, if an enrollee were to experience a change in county of residence, household income, household size, or other factors related to the BHP payment determination during the quarter, the payment for the quarter would be based on the data as of the beginning of the quarter. Payments would still be made only for months that the person is enrolled in and eligible for the BHP. We do not anticipate that this would have a significant effect on the federal BHP payment. The states must maintain data that are consistent with CMS' verification requirements, including auditable records for each individual enrolled, indicating an eligibility determination and a determination of income and other criteria relevant to the payment methodology as of the beginning of each quarter.

<sup>4</sup> The three lowest income ranges would be limited to lawfully present immigrants who are ineligible for Medicaid because of immigration status.

As described in § 600.610 (Secretarial determination of BHP payment amount), the state is required to submit certain data in accordance with this notice. We require that this data be collected and validated by states operating a BHP, and that this data be submitted to CMS.

#### *D. Discussion of Specific Variables Used in Payment Equations*

##### 1. Reference Premium (RP)

To calculate the estimated PTC that would be paid if BHP-eligible individuals enrolled in QHPs through an Exchange, we must calculate a RP because the PTC is based, in part, on the premiums for the applicable second lowest cost silver plan as explained in section II.C.4 of this notice, regarding the Premium Tax Credit Formula (PTCF). The proposal is unchanged from the current method except to update the reference years, and to provide additional methodological details to simplify calculations and to deal with potential ambiguities. Accordingly, for the purposes of calculating the BHP payment rates, the RP, in accordance with 26 U.S.C. 36B(b)(3)(C), is defined as the adjusted monthly premium for an applicable second lowest cost silver plan. The applicable second lowest cost silver plan is defined in 26 U.S.C. 36B(b)(3)(B) as the second lowest cost silver plan of the individual market in the rating area in which the taxpayer resides that is offered through the same Exchange. We propose to use the adjusted monthly premium for an applicable second lowest cost silver plan in the applicable program year (2019 or 2020) as the RP (except in the case of a state that elects to use the prior plan year's premium as the basis for the federal BHP payment for 2019 or 2020, as described in section II.F of this notice).

The RP would be the premium applicable to non-tobacco users. This is consistent with the provision in 26 U.S.C. 36B(b)(3)(C) that bases the PTC on premiums that are adjusted for age alone, without regard to tobacco use, even for states that allow insurers to vary premiums based on tobacco use in accordance with 42 U.S.C. 300gg(a)(1)(A)(iv).

Consistent with the policy set forth in 26 CFR 1.36B-3(f)(6), to calculate the PTC for those enrolled in a QHP through an Exchange, we propose not to update the payment methodology, and subsequently the federal BHP payment rates, in the event that the second lowest cost silver plan used as the RP, or the lowest cost silver plan, changes (that is, terminates or closes enrollment during the year).

The applicable second lowest cost silver plan premium will be included in the BHP payment methodology by age range, geographic area, and self-only or applicable category of family coverage obtained through the BHP.

We note that the choice of the second lowest cost silver plan for calculating BHP payments would rely on several simplifying assumptions in its selection. For the purposes of determining the second lowest cost silver plan for calculating PTC for a person enrolled in a QHP through an Exchange, the applicable plan may differ for various reasons. For example, a different second lowest cost silver plan may apply to a family consisting of 2 adults, their child, and their niece than to a family with 2 adults and their children, because 1 or more QHPs in the family's geographic area might not offer family coverage that includes the niece. We believe that it would not be possible to replicate such variations for calculating the BHP payment and believe that in the aggregate, they would not result in a significant difference in the payment. Thus, we propose to use the second lowest cost silver plan available to any enrollee for a given age, geographic area, and coverage category.

This choice of RP relies on an assumption about enrollment in the Exchanges. In previous methodologies, we had assumed that all persons enrolled in the BHP would have elected to enroll in a silver level plan if they had instead enrolled in a QHP through an Exchange (and that the QHP premium would not be lower than the value of the PTC). While we propose to continue to use the second-lowest cost silver plan premium as the RP, we are proposing in this methodology to change the assumption about which metal-tier plans enrollees would choose (see the section on the metal-tier selection factor (MTSF) in this methodology).

We do not believe it is appropriate to adjust the payment for an assumption that some BHP enrollees would not have enrolled in QHPs for purposes of calculating the BHP payment rates, since section 1331(d)(3)(A)(ii) of the Affordable Care Act requires the calculation of such rates as if the enrollee had enrolled in a QHP through an Exchange.

The applicable age bracket will be one dimension of each rate cell. We propose to assume a uniform distribution of ages and estimate the average premium amount within each rate cell. We believe that assuming a uniform distribution of ages within these ranges is a reasonable approach and would produce a reliable determination of the

total monthly payment for BHP enrollees. We also believe this approach would avoid potential inaccuracies that could otherwise occur in relatively small payment cells if age distribution were measured by the number of persons eligible or enrolled.

We propose to use geographic areas based on the rating areas used in the Exchanges. We propose to define each geographic area so that the RP is the same throughout the geographic area. When the RP varies within a rating area, we propose defining geographic areas as aggregations of counties with the same RP. Although plans are allowed to serve geographic areas smaller than counties after obtaining our approval, we propose that no geographic area, for purposes of defining BHP payment rate cells, will be smaller than a county. We do not believe that this assumption will have a significant impact on federal payment levels and it would likely simplify both the calculation of BHP payment rates and the operation of the BHP.

Finally, in terms of the coverage category, we propose that federal payment rates only recognize self-only and two-adult coverage, with exceptions that account for children who are potentially eligible for the BHP. First, in states that set the upper income threshold for children's Medicaid and CHIP eligibility below 200 percent of FPL (based on modified adjusted gross income (MAGI), children in households with incomes between that threshold and 200 percent of FPL would be potentially eligible for the BHP. Currently, the only states in this category are Idaho and North Dakota.<sup>5</sup> Second, the BHP would include lawfully present immigrant children with household incomes at or below 200 percent of FPL in states that have not exercised the option under the sections 1903(v)(4)(A)(ii) and 2107(e)(1)(E) of the Act to qualify all otherwise eligible, lawfully present immigrant children for Medicaid and CHIP. States that fall within these exceptions would be identified based on their Medicaid and CHIP State Plans, and the rate cells would include appropriate categories of BHP family coverage for children. For example, Idaho's Medicaid and CHIP eligibility is limited to families with MAGI at or below 185 percent FPL. If Idaho implemented a BHP, Idaho children with household incomes between 185 and 200 percent could qualify. In other states, BHP eligibility will generally be restricted to adults, since children who are citizens or lawfully present immigrants and live in

<sup>5</sup> CMCS. "State Medicaid, CHIP and BHP Income Eligibility Standards Effective April 1, 2018."

households with incomes at or below 200 percent of FPL will qualify for Medicaid or CHIP, and thus be ineligible for a BHP under section 1331 (e)(1)(C) of the Affordable Care Act, which limits a BHP to individuals who are ineligible for minimum essential coverage (as defined in section 5000A(f) of the Internal Revenue Code of 1986).

## 2. Premium Adjustment Factor (PAF)

The PAF considers the premium increases in other states that took effect after we discontinued payments to issuers for CSRs provided to enrollees in QHPs offered through Exchanges.

Despite the discontinuance of federal payments for CSRs, QHPs are required to provide CSRs to eligible enrollees. As a result, QHPs frequently increased the silver-level plan premiums to account for those additional costs; adjustments and how those were applied (for example, to only silver-level plans or to all metal-tier plans) varied across states. For the states operating BHPs in 2018, the adjustments were relatively minor, because the majority of enrollees eligible for CSRs (and all who were eligible for the largest CSRs) were enrolled in the BHP and not in QHPs on the Exchanges.

In the Final Administrative Order, we incorporated the PAF into the BHP payment methodology for 2018. We propose to include this factor in the 2019 and 2020 payment methodologies, and to use the same value for the factor as in the Final Administrative Order.

Under the Final Administrative Order, we calculated the PAF for each BHP state by using information requested from QHP issuers in each state and the District of Columbia, and determined the premium adjustment that the responding QHP issuers made to each silver level plan in 2018 to account for the discontinuation of CSR payments to QHP issuers. Based on the data collected, we estimated the median adjustment for silver level QHPs nationwide (excluding those in the two BHP states). To the extent that QHP issuers made no adjustment (or the adjustment was 0), this would be counted as 0 in determining the median adjustment made to all silver level QHPs nationwide. If the amount of the adjustment was unknown—or we determined that it should be excluded for methodological reasons (for example, the adjustment was negative, an outlier, or unreasonable)—then we did not count the adjustment towards determining the median adjustment.<sup>6</sup>

For each of the two BHP states, we determined the median adjustment for all silver level QHPs in that state. The PAF for each BHP state equaled 1 plus the nationwide median adjustment divided by 1 plus the state median adjustment for the BHP state. In other words,

$$\text{PAF} = (1 + \text{Nationwide Median Adjustment}) \div (1 + \text{State Median Adjustment})$$

To determine the PAF described above, we requested information from QHP issuers in each state serviced by a Federally-facilitated Exchange (FFE) to determine the premium adjustment those issuers made to each silver level plan offered through the Exchange in 2018 to account for the end of CSR payments. Specifically, we requested information showing the percentage change that QHP issuers made to the premium for each of their silver level plans to cover benefit expenditures associated with the CSRs, given the lack of CSR payments in 2018. This percentage change was a portion of the overall premium increase from 2017 to 2018.

According to our records, there are 1,233 silver-level QHPs operating on Exchanges in 2018. Of these 1,233 QHPs, 318 QHPs (25.8 percent) responded to our request for the percentage adjustment applied to silver-level QHP premiums in 2018 to account for the discontinuance of the CSRs. These 318 QHPs operated in 26 different states, with 10 of those states running State-based Exchanges (SBEs), working in partnership with us to implement the FFE in their state in 2018. Thirteen of these 318 QHPs were in New York (and none were in Minnesota). Excluding these 13 QHPs from the analysis, the nationwide median adjustment was 20.0 percent. Of the 13 QHPs in New York that responded, the state median adjustment was 1.0 percent. We believe that this is an appropriate adjustment for QHPs in Minnesota as well, based on the observed changes in New York's QHP premiums in response to the CSR adjustment (and the operation of the BHP in that state) and our analysis of expected QHP premium adjustments for states with BHPs. We calculated the proposed PAF as  $(1 + 20\%) \div (1 + 1\%)$  (or 1.20/1.01), which results in a value of 1.188.

We propose that the PAF continue to be set to 1.188 for 2019 and 2020. We believe that this value for the PAF continues to reasonably account for the increase in silver-level premiums

experienced in non-BHP states that is associated with the discontinuance of the CSR payments. The impact can reasonably be expected to be similar to that in 2018, because the unavailability of CSR payments has not changed. We welcome comments on this factor and its development.

## 3. Population Health Factor (PHF)

We propose that the PHF be included in the methodology to account for the potential differences in the average health status between BHP enrollees and persons enrolled through the Exchanges. To the extent that BHP enrollees would have been enrolled through an Exchange in the absence of a BHP in a state, the exclusion of those BHP enrollees in the Exchange may affect the average health status of the overall population and the expected QHP premiums. Our proposal continues the methodology currently in place, except to update reference years.

We currently do not believe that there is evidence that the BHP population would have better or poorer health status than the Exchange population. At this time, there is a lack of experience available in the Exchanges that limits the ability to analyze the health differences between these groups of enrollees. Exchanges have been in operation since 2014, and 2 states have operated BHPs in 2015, 2016, 2017, and 2018, but we do not have the data available to do the analysis necessary to make this adjustment at this time. In addition, differences in population health may vary across states. Thus, at this time, we believe that it is not feasible to develop a methodology to make a prospective adjustment to the PHF that is reliably accurate, consistent with the methodology described in previous notices. We will consider updating the methodology in future years when information becomes available.

Given these analytic challenges and the limited data about Exchange coverage and the characteristics of BHP-eligible consumers that will be available by the time we establish federal payment rates, we believe that the most appropriate adjustment for 2019 would be 1.00. We also propose that the adjustment for 2020 would remain at 1.00.

In the previous BHP payment methodologies, we included an option for states to include a retrospective population health status adjustment. We propose that states be provided with the same option for 2019 and 2020 to include a retrospective population health status adjustment in the certified methodology, which is subject to our

<sup>6</sup> Some examples of outliers or unreasonable adjustments include (but are not limited to) values over 100 percent (implying the premiums doubled

or more as a result of the adjustment), values more than double the otherwise highest adjustment, or non-numerical entries.

review and approval. This option is described further in section II.G of this notice. Regardless of whether a state elects to include a retrospective population health status adjustment, we anticipate that, in future years, when additional data becomes available about Exchange coverage and the characteristics of BHP enrollees, we may estimate the PHF differently.

While the statute requires consideration of risk adjustment payments and reinsurance payments insofar as they would have affected the PTC that would have been provided to BHP-eligible individuals had they enrolled in QHPs, we are not proposing to require that a BHP's standard health plans receive such payments. As explained in the BHP final rule, BHP standard health plans are not included in the risk adjustment program operated by HHS on behalf of states. Further, standard health plans do not qualify for payments from the transitional reinsurance program established under section 1341 of the Affordable Care Act.<sup>7</sup> To the extent that a state operating a BHP determines that, because of the distinctive risk profile of BHP-eligible consumers, BHP standard health plans should be included in mechanisms that share risk with other plans in the state's individual market, the state would need to use other methods for achieving this goal.

#### 4. Household Income (I)

Household income is a significant determinant of the amount of the PTC that is provided for persons enrolled in a QHP through an Exchange. Accordingly, both the current and proposed BHP payment methodologies incorporate household income into the calculations of the payment rates through the use of income-based rate cells. We propose defining household income in accordance with the definition of MAGI in 26 U.S.C. 36B(d)(2)(B) and consistent with the definition in 45 CFR 155.300. Income would be measured relative to the FPL, which is updated periodically in the

<sup>7</sup> See 45 CFR 153.400(a)(2)(iv) (BHP standard health plans are not required to submit reinsurance contributions), 153.20 (definition of "Reinsurance-eligible plan" as not including "health insurance coverage not required to submit reinsurance contributions"), 153.230(a) (reinsurance payments under the national reinsurance parameters are available only for "Reinsurance-eligible plans").

**Federal Register** by the Secretary under the authority of 42 U.S.C. 9902(2), based on annual changes in the consumer price index for all urban consumers (CPI-U). In our proposed methodology, household size and income as a percentage of FPL would be used as factors in developing the rate cells. We propose using the following income ranges measured as a percentage of FPL:<sup>8</sup>

- 0–50 percent.
- 51–100 percent.
- 101–138 percent.
- 139–150 percent.
- 151–175 percent.
- 176–200 percent.

We further propose to assume a uniform income distribution for each federal BHP payment cell. We believe that assuming a uniform income distribution for the income ranges proposed would be reasonably accurate for the purposes of calculating the BHP payment and would avoid potential errors that could result if other sources of data were used to estimate the specific income distribution of persons who are eligible for or enrolled in the BHP within rate cells that may be relatively small.

Thus, when calculating the mean, or average, PTC for a rate cell, we propose to calculate the value of the PTC at each 1 percentage point interval of the income range for each federal BHP payment cell and then calculate the average of the PTC across all intervals. This calculation would rely on the PTC formula described in section II.D.4 of this notice.

As the advance payment of PTC (APTC) for persons enrolled in QHPs would be calculated based on their household income during the open enrollment period, and that income would be measured against the FPL at that time, we propose to adjust the FPL by multiplying the FPL by a projected increase in the CPI-U between the time that the BHP payment rates are calculated and the QHP open enrollment period, if the FPL is expected to be updated during that time. We propose that the projected increase in the CPI-U would be based on the

<sup>8</sup> These income ranges and this analysis of income apply to the calculation of the PTC. Many fewer income ranges and a much simpler analysis apply in determining the value of CSRs, as specified below.

intermediate inflation forecasts from the most recent OASDI and Medicare Trustees Reports.<sup>9</sup>

#### 5. Premium Tax Credit Formula (PTCF)

In Equation 1 described in section II.A.1 of this notice, we propose to use the formula described in 26 U.S.C. 36B(b) to calculate the estimated PTC that would be paid on behalf of a person enrolled in a QHP on an Exchange as part of the BHP payment methodology. This formula is used to determine the contribution amount (the amount of premium that an individual or household theoretically would be required to pay for coverage in a QHP on an Exchange), which is based on (A) the household income; (B) the household income as a percentage of FPL for the family size; and (C) the schedule specified in 26 U.S.C. 36B(b)(3)(A) and shown below. The difference between the contribution amount and the adjusted monthly premium for the applicable second lowest cost silver plan is the estimated amount of the PTC that would be provided for the enrollee.

The PTC amount provided for a person enrolled in a QHP through an Exchange is calculated in accordance with the methodology described in 26 U.S.C. 36B(b)(2). The amount is equal to the lesser of the premium for the plan in which the person or household enrolls, or the adjusted premium for the applicable second lowest cost silver plan minus the contribution amount.

The applicable percentage is defined in 26 U.S.C. 36B(b)(3)(A) and 26 CFR 1.36B-3(g) as the percentage that applies to a taxpayer's household income that is within an income tier specified in Tables 1 and 2, increasing on a sliding scale in a linear manner from an initial premium percentage to a final premium percentage specified in Tables 1 and 2. We propose no changes to this methodology. The applicable percentages in Table 1 for calendar year (CY) 2018 would be effective for BHP program year 2019, and the applicable percentages in Table 2 for CY 2019 would be effective for BHP program year 2020.

<sup>9</sup> See Table IV A1 from the 2018 reports in <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports-TrustFunds/Downloads/TR2018.pdf>.

TABLE 1—APPLICABLE PERCENTAGE TABLE FOR CY 2018<sup>a</sup>

In the case of household income (expressed as a percent of poverty line) within the following income tier:	The initial premium percentage is—	The final premium percentage is—
Up to 133% .....	2.01	2.01
133% but less than 150% .....	3.02	4.03
150% but less than 200% .....	4.03	6.34
200% but less than 250% .....	6.34	8.10
250% but less than 300% .....	8.10	9.56
300% but not more than 400% .....	9.56	9.56

<sup>a</sup> IRS Revenue Procedure 2017–36. <https://www.irs.gov/pub/irs-drop/rp-17-36.pdf>.

TABLE 2—APPLICABLE PERCENTAGE TABLE FOR CY 2019<sup>b</sup>

In the case of household income (expressed as a percent of poverty line) within the following income tier:	The initial premium percentage is—	The final premium percentage is—
Up to 133% .....	2.08	2.08
133% but less than 150% .....	3.11	4.15
150% but less than 200% .....	4.15	6.54
200% but less than 250% .....	6.54	8.36
250% but less than 300% .....	8.36	9.86
300% but not more than 400% .....	9.86	9.86

<sup>b</sup> IRS Revenue Procedure 2018–34. <https://www.irs.gov/pub/irs-drop/rp-18-34.pdf>.

The applicable percentages for CY 2018 (Table 1) would be used for the 2019 payment methodology, and the applicable percentages for CY 2019 (Table 2) would be used for the 2020 payment methodology. The applicable percentages will be updated in future years in accordance with 26 U.S.C. 36B (b)(3)(A)(ii).

#### 6. Metal-Tier Selection Factor (MTSF)

On the Exchange, if an enrollee chooses a QHP and the value of the PTC is greater than the premium, then the PTC is reduced to be equal to the premium. This usually occurs when enrollees eligible for larger PTCs (generally those with lower household incomes or older enrollees) choose bronze-level plans, which have the lowest premiums on the Exchange. Prior to 2018, we believed that the impact of these choices were relatively small on the amount of PTCs that the federal government paid. Most enrollees in income ranges up to 200 percent FPL chose silver-level plans, and in most cases where enrollees chose bronze-level plans, the premium was still more than the PTC. Therefore, we made no adjustment for enrollees choosing non-silver-level plans in developing the BHP payment methodology.

After the discontinuance of the CSR payments in October 2017, several changes occurred that increased the expected impact of enrollees' plan choices on the amount of PTC paid. Silver-level QHP premiums for the 2018

benefit year increased substantially relative to other metal-tier plans in many states (on average, by about 20 percent). We believe this contributed to an increase in the percentage of enrollees with lower incomes choosing bronze-level plans, despite being eligible for CSRs in silver-level plans, because many were able to purchase plans and pay \$0 in premium; according to CMS data, the percentage of persons with incomes between 0 percent and 200 percent of FPL eligible for CSRs (those who would be eligible for the BHP if the state operated a BHP) selecting bronze plans increased from about 11 percent in 2017 to about 13 percent in 2018. In addition, the likelihood that a person choosing a bronze-level plan would pay \$0 premium increased (and the difference between the bronze-level QHP premium and the available PTC widened). Between 2017 and 2018, the ratio of the average silver plan premium to the average bronze plan premium increased from about 117 percent to 133 percent; that is, the average silver plan premium was 17 percent higher than the average bronze plan premium in 2017, and the average silver plan premium was 33 percent higher than the average bronze plan premium in 2018. Similarly, the average estimated reduction in APTC for enrollees with incomes between 0 percent and 200 percent FPL that chose bronze plan increased from about 11 percent in 2017 to about 23 percent in 2018 (after adjusting for the average age

of bronze plan and silver plan enrollees); that is, in 2017, enrollees with incomes in this range who chose bronze plans received 11 percent less than the full value of the APTC, and in 2018, those enrollees who chose bronze plans received 23 percent less than the full value of the APTC. The discontinuance of the CSR payments led to increases in silver plan premiums (and thus in the total potential PTCs), but did not generally increase the bronze plan premiums in most states; we believe this is the primary reason for the increase in the percentage reduction in PTCs paid for those who enrolled in bronze plans between 2017 and 2018. Therefore, we now believe that the impacts on the amount of PTC the government would pay due to enrollees' plan choices are larger and thus more significant, and we are proposing to include an adjustment in the BHP payment methodology to account for this (the MTSF). Section 1331(d)(3) of the Affordable Care Act requires that the BHP payments to states be based on what would have been provided if such eligible individuals were allowed to enroll in QHPs, and we believe that it is appropriate to consider how individuals would have chosen different plans—including across different metal tiers—as part of the BHP payment methodology.

We propose to calculate the MTSF using the following approach. First, we would calculate the percentage of enrollees with incomes below 200

percent of the FPL (those who would be potentially eligible for the BHP) in non-BHP states who enrolled in bronze-level plans in 2018. Second, we would calculate the ratio of the average PTC paid for enrollees in this income range who selected bronze-level plans compared to the average PTC paid for enrollees in the same income range who selected silver-level plans. Both of these calculations would be done using CMS data on Exchange enrollment and payments.

The MTSF would then be set to the value of 1 minus the product of the percentage of enrollees who chose bronze-level plans and 1 minus the ratio of the average PTC paid for enrollees in bronze-level plans to the average PTC paid for enrollees in silver-level plans:

$$MTSF = 1 - (\text{percentage of enrollees in bronze-level plans} \times (1 - \text{average PTC paid for bronze-level enrollees} / \text{average PTC paid for silver-level enrollees}))$$

We have calculated that 12.68 percent of enrollees in households with incomes below 200 percent of the FPL selected bronze-level plans in 2018, and that those enrollees received average PTCs equal to 76.66 percent of the average PTCs paid for enrollees in silver-level plans (the average PTC was 27.04 lower for those who selected bronze plans, but after adjusting for the average age of bronze and silver plans enrollees, the difference was reduced to 23.34 percent). Therefore, we propose that the value of the MTSF for 2019 would be 97.04 percent. We also propose to update this with 2019 data for 2020.

We welcome comments on this factor and the determination of the value.

#### 7. Income Reconciliation Factor (IRF)

For persons enrolled in a QHP through an Exchange who receive APTC, there will be an annual reconciliation following the end of the year to compare the advance payments to the correct amount of PTC based on household circumstances shown on the federal income tax return. Any difference between the latter amounts and the advance payments made during the year would either be paid to the taxpayer (if too little APTC was paid) or charged to the taxpayer as additional tax (if too much APTC was made, subject to any limitations in statute or regulation), as provided in 26 U.S.C. 36B(f).

Section 1331(e)(2) of the Affordable Care Act specifies that an individual eligible for the BHP may not be treated as a qualified individual under section 1312 who is eligible for enrollment in a QHP offered through an Exchange. We are defining "eligible" to mean anyone for whom the state agency or the Exchange assesses or determines, based

on the single streamlined application or renewal form, as eligible for enrollment in the BHP. Because enrollment in a QHP is a requirement for individuals to receive PTC, individuals determined or assessed as eligible for a BHP are not eligible to receive APTC assistance for coverage in the Exchange. Because they do not receive APTC assistance, BHP enrollees, on whom the BHP payment methodology is based, are not subject to the same income reconciliation as Exchange consumers. Nonetheless, there may still be differences between a BHP enrollee's household income reported at the beginning of the year and the actual household income over the year. These may include small changes (reflecting changes in hourly wage rates, hours worked per week, and other fluctuations in income during the year) and large changes (reflecting significant changes in employment status, hourly wage rates, or substantial fluctuations in income). There may also be changes in household composition. Thus, we believe that using unadjusted income as reported prior to the BHP program year may result in calculations of estimated PTC that are inconsistent with the actual household incomes of BHP enrollees during the year. Even if the BHP adjusts household income determinations and corresponding claims of federal payment amounts based on household reports during the year or data from third-party sources, such adjustments may not fully capture the effects of tax reconciliation that BHP enrollees would have experienced had they been enrolled in a QHP through an Exchange and received APTC assistance.

Therefore, in accordance with current practice, we propose including in Equation 1 an income adjustment factor that would account for the difference between calculating estimated PTC using: (a) Household income relative to FPL as determined at initial application and potentially revised mid-year under § 600.320, for purposes of determining BHP eligibility and claiming federal BHP payments; and (b) actual household income relative to FPL received during the plan year, as it would be reflected on individual federal income tax returns. This adjustment would seek prospectively to capture the average effect of income reconciliation aggregated across the BHP population had those BHP enrollees been subject to tax reconciliation after receiving APTC assistance for coverage provided through QHPs. Consistent with the methodology used in past years, we propose estimating reconciliation effects based on tax data for 2 years, reflecting

income and tax unit composition changes over time among BHP-eligible individuals.

The OTA maintains a model that combines detailed tax and other data, including Exchange enrollment and PTC claimed, to project Exchange premiums, enrollment, and tax credits. For each enrollee, this model compares the APTC based on household income and family size estimated at the point of enrollment with the PTC based on household income and family size reported at the end of the tax year. The former reflects the determination using enrollee information furnished by the applicant and tax data furnished by the IRS. The latter would reflect the PTC eligibility based on information on the tax return, which would have been determined if the individual had not enrolled in the BHP. We propose that the ratio of the reconciled PTC to the initial estimation of PTC would be used as the IRF in Equation (1) for estimating the PTC portion of the BHP payment rate.

For 2018, OTA estimated that the IRF for states that have implemented the Medicaid eligibility expansion to cover adults up to 133 percent of the FPL will be 97.37 percent, and for states that have not implemented the Medicaid eligibility expansion and do not cover adults up to 133 percent of the FPL will be 97.45 percent. In the 2018 payment methodology, the IRF will be equal to 97.41 percent (this was previously published in the CMCS Informational Bulletin "Basic Health Program; Federal Funding Methodology for Program Year 2018" on May 17, 2017). We propose updating this calculation and the IRF for 2019 and for 2020.

#### E. State Option To Use Prior Program Year QHP Premiums for BHP Payments

In the interest of allowing states greater certainty in the total BHP federal payments for a given plan year, we have given states the option to have their final federal BHP payment rates calculated using a projected ARP (that is, using premium data from the prior program year multiplied by the PTF defined below), as described in Equation (2b). Under the 2016 BHP payment notice, states were required to make their election for the 2017 program year by May 15, 2016 and to make their election for the 2018 program year by May 15, 2017. We propose that states generally continue to meet the deadline of making their election by May 15 of the year preceding the applicable program year. However, because we are proposing to revise the 2019 payment methodology after the May 15, 2018 deadline has passed, we are proposing that a state may change its

election for the 2019 program year, provided that it does so within 30 days of the date of the notice announcing the final BHP payment methodology for 2019. A change in the state's election would be effective retroactive to January 1, 2019. For 2020, the state would need to inform us no later than May 15, 2019 of its decision for the 2020 program year. (If the final methodology is published after this deadline, we may extend this deadline to give states the opportunity to make this election.)

For Equation (2b), we propose to continue to define the PTF, with minor changes in calculation sources and methods, as follows:

*PTF*: In Equation (2b), we propose to calculate an ARP based on the application of certain relevant variables to the RP, including a PTF. In the case of a state that would elect to use the 2018 premiums as the basis for determining the 2019 BHP payment, for example, it would be appropriate to apply a factor that would account for the change in health care costs between the year of the premium data and the BHP program year. We are proposing to define this as the PTF in the BHP payment methodology. This factor would approximate the change in health care costs per enrollee, which would include, but not be limited to, changes in the price of health care services and changes in the utilization of health care services. This would provide an estimate of the adjusted monthly premium for the applicable second lowest cost silver plan that would be more accurate and reflective of health care costs in the BHP program year.

For the PTF, we propose to use the annual growth rate in private health insurance expenditures per enrollee from the National Health Expenditure (NHE) projections, developed by the Office of the Actuary in CMS (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>). For BHP program year 2019, we propose that the PTF would be 3.8 percent.

States may want to consider that the increase in premiums for QHPs from one year to the next may differ from the PTF developed for the BHP funding methodology for several reasons. In particular, states may want to consider that the second lowest cost silver plan may be different from one year to the next. This may lead to the PTF being greater than or less than the actual change in the premium of the second lowest cost silver plan.

#### *F. State Option To Include Retrospective State-Specific Health Risk Adjustment in Certified Methodology*

To determine whether the potential difference in health status between BHP enrollees and consumers in the Exchange would affect the PTC, risk adjustment payments that would have otherwise been made had BHP enrollees been enrolled in coverage through an Exchange, we propose to continue to provide states implementing the BHP the option to propose and to implement, as part of the certified methodology, a retrospective adjustment to the federal BHP payments to reflect the actual value that would be assigned to the PHF (or risk adjustment) based on data accumulated during that program year for each rate cell.

We acknowledge that there is uncertainty with respect to this factor due to the lack of experience of QHPs through an Exchange and other payments related to the Exchange, which is why, absent a state election, we propose to use a value for the PHF to determine a prospective payment rate which assumes no difference in the health status of BHP enrollees and QHP enrollees. There is considerable uncertainty regarding whether the BHP enrollees will pose a greater risk or a lesser risk compared to the QHP enrollees, how to best measure such risk, the potential effect such risk would have had on PTC, and risk adjustment that would have otherwise been made had BHP enrollees been enrolled in coverage through an Exchange. To the extent, however, that a state would develop an approved protocol to collect data and effectively measure the relative risk and the effect on federal payments, we propose to permit a retrospective adjustment that would measure the actual difference in risk between the two populations to be incorporated into the certified BHP payment methodology and used to adjust payments in the previous year.

For a state electing the option to implement a retrospective population health status adjustment, we propose requiring the state to submit a proposed protocol to CMS, which would be subject to approval by us and would be required to be certified by the Chief Actuary of CMS, in consultation with the OTA, as part of the BHP payment methodology. We describe the protocol for the population health status adjustment in guidance in *Considerations for Health Risk Adjustment in the Basic Health Program in Program Year 2015* (<http://www.medicaid.gov/Basic-Health-Program/Downloads/Risk-Adjustment->

*and-BHP-White-Paper.pdf*). Under the February 2016 BHP payment notice, states were required to submit a proposed protocol by August 1, 2017 for the 2018 program year. We propose requiring a state to submit its proposed protocol within 60 days of the publication of the final payment methodology for our approval for the 2019 program year, and by August 1, 2019 for the 2020 program year. This submission would also include descriptions of how the state would collect the necessary data to determine the adjustment, including any contracting contingencies that may be in place with participating standard health plan issuers. We would provide technical assistance to states as they develop their protocols. To implement the population health status, we propose that we must approve the state's protocol no later than 90 days after the submission of the PHF methodology for the 2019 program year, and by December 31, 2019 for the 2020 program year. Finally, we propose that the state be required to complete the population health status adjustment at the end of the program year based on the approved protocol. After the end of the program year, and once data is made available, we propose to review the state's findings, consistent with the approved protocol, and make any necessary adjustments to the state's federal BHP payment amounts. If we determine that the federal BHP payments were less than they would have been using the final adjustment factor, we would apply the difference to the state's next quarterly BHP trust fund deposit. If we determine that the federal BHP payments were more than they would have been using the final reconciled factor, we would subtract the difference from the next quarterly BHP payment to the state.

#### **III. Collection of Information Requirements**

This notice's proposed methodology is similar to the methodology originally published in the February 2016 payment notice and modified by the Final Administrative Order. The proposed methodology changes would not revise or impose any additional reporting, recordkeeping, or third-party disclosure requirements or burden on QHPs or on states operating State-based Exchanges. The methodology's information collection requirements and burden estimates are approved by OMB under control number 0938-1218 (CMS-10510). The proposed methodology would not necessitate the need to make any changes under that control number.

**IV. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

**V. Regulatory Impact Analysis**

*A. Statement of Need*

Section 1331 of the Affordable Care Act (codified at 42 U.S.C. 18051) requires the Secretary to establish a BHP, and section (d)(1) specifically provides that if the Secretary finds that a state meets the requirements of the program established under section (a) of section 1331 of the Affordable Care Act, the Secretary shall transfer to the State federal BHP payments described in section (d)(3). This proposed methodology provides for the funding methodology to determine the federal BHP payment amounts required to implement these provisions in program years 2019 and 2020.

*B. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order

12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) (Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As noted in the BHP final rule, the BHP provides the flexibility to establish an alternative coverage program for low-income individuals who would otherwise be eligible to purchase coverage through the Marketplace. To date, two states have established a BHP, and we expect state participation to remain static as a result of this payment methodology. However, the proposed payment methodology differs from prior years’ methodologies as the MTSF is incorporated and would reduce BHP payments compared to using the previous year’s methodology. We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

The aggregate economic impact of this proposed payment methodology is estimated to be \$300 million from CY 2019 through 2020 (measured in real 2019 dollars). For the purposes of this analysis, we have assumed that 2 states would implement BHP in 2019 and 2020. This assumption is based on the fact that two states have established a BHP to date, and we do not have any indication that additional states may

implement the program. We also assumed there would be about 802,000 BHP enrollees in 2019 (based on the most recent state estimates of enrollment as of October 2018) and about 806,000 in 2020. The size of the BHP depends on several factors, including the number of and which particular states choose to implement or continue a BHP, the level of QHP premiums, and the other coverage options for persons who would be eligible for the BHP. In particular, while we generally expect that many enrollees would have otherwise been enrolled in a QHP through the Marketplace, some persons may have been eligible for Medicaid under a waiver or a state health coverage program. For those who would have enrolled in a QHP and thus would have received PTCs, the federal expenditures for the BHP would be expected to be more than offset by a reduction in federal expenditures for PTCs. For those who would have been enrolled in Medicaid, there would likely be a smaller offset in federal expenditures (to account for the federal share of Medicaid expenditures), and for those who would have been covered in non-federal programs or would have been uninsured, there likely would be an increase in federal expenditures.

Projected BHP enrollment and expenditures under the previous payment methodology were calculated using the most recent 2018 QHP premiums and state estimates for BHP enrollment. Enrollment was projected to 2019 using the projected increase in the number of adults in the U.S. from 2018 to 2019 (0.5 percent), and premiums were projected using the NHE projection of premiums for private health insurance. Expenditures are in real 2019 dollars and are deflated using the projected change in the medical component of the consumer price index (CPI–M). Expenditures are projected to be \$4.890 billion in 2019 and \$4.944 billion in 2020.

For the change in the methodology to incorporate the MTSF, the MTSF was calculated as having a value of 97.04 percent (as described previously). This reduced projected expenditures by \$149 million in 2019 and \$151 million in 2020, compared to projected expenditures using the methodology in the 2018 Final Administrative Order.

**TABLE 3—ESTIMATED FEDERAL IMPACTS FOR THE BASIC HEALTH PROGRAM 2019 AND 2020 PAYMENT METHODOLOGY**  
[Millions of 2019 dollars]

	2019	2020
Projected Federal BHP payments under 2018 Final Administrative Order .....	\$5,040	\$5,094
Projected Federal BHP payments under proposed methodology .....	4,890	4,944

TABLE 3—ESTIMATED FEDERAL IMPACTS FOR THE BASIC HEALTH PROGRAM 2019 AND 2020 PAYMENT METHODOLOGY—  
Continued  
[Millions of 2019 dollars]

	2019	2020
Federal savings under proposed methodology .....	149	151

### C. Anticipated Effects

The proposed change in the BHP methodology is expected to shift a portion of BHP costs from the Federal government to the state operating a BHP. Currently, we understand that states pay a portion of the BHP costs each year. This increase in costs may lead the states to consider a combination of the following changes: Increasing state payments to the BHP; increasing beneficiary premiums and cost-sharing to the BHP; and reducing payment rates to standard health plans. Beneficiary premiums and cost-sharing are limited under the BHP, so it is unlikely states could make up much of the difference through increased beneficiary contributions. We expect that most of the difference in federal payments would be made up through increases in state funding.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The Act generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. Individuals and states are not included in the definition of a small entity.

Because this proposed methodology is focused solely on federal BHP payment rates to states, it does not contain provisions that would have a direct impact on hospitals, physicians, and other health care providers that are designated as small entities under the RFA. Accordingly, we have determined that the proposed methodology, like the current methodology and the final rule that established the BHP, will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of

section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. For the preceding reasons, the Secretary has determined that this proposed methodology will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. States have the option, but are not required, to establish a BHP. Further, the proposed methodology would establish federal payment rates without requiring states to provide the Secretary with any data not already required by other provisions of the Affordable Care Act or its implementing regulations. Thus, neither the current nor the proposed payment methodologies mandate expenditures by state governments, local governments, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The BHP is entirely optional for states, and if implemented in a state, provides access to a pool of funding that would not otherwise be available to the state. This requirement unlike the preceding requirement excludes the impact on the private sectors.

### D. Alternatives Approaches

Given the absence of an appropriation for federal CSR payments, we considered several alternatives of how to consider this in the BHP payment methodology for 2019 and 2020, following the Final Administrative Order. In States without BHPs, there were increases in the silver plan premiums due to the lack of federal funding for CSRs in 2018, and those are

expected to remain in the rates in 2019 and 2020 (absent federal funding for CSRs). QHP issuers are still responsible for CSRs on behalf of eligible enrollees, regardless of federal funding; therefore, in many States QHP issuers have increased premiums significantly to account for the costs of the CSRs in 2018 and are expected to continue to do so in subsequent years. In states operating BHPs, the majority of the individuals eligible for CSRs (and the vast majority eligible for the largest CSRs) are enrolled in the BHP and not in the Exchange. As a result, in those states, QHP issuers made much smaller adjustments to premiums to account for CSR costs in 2018. We considered whether or not to make an adjustment in the BHP payment methodology for how much QHP premiums would have increased if BHP enrollees had been enrolled through the Exchange instead as part of the Final Administrative Order. We are also considering other methodologies for calculating the adjustment, including using program data to estimate the expected adjustment and to request information from QHPs and/or states for 2019 and 2020 QHP premiums. We are proposing to use the same methodology, data, and adjustment to the premiums as was used in the 2018 payment methodology described in the Final Administrative Order. (See section II.D.2 for more information.)

We are also considering whether or not to make an adjustment to account for the number of enrollees who would select other metal-tier plans on the Exchange (if not for the existence of the BHP) and the impact that this would have on the average PTC paid. In previous methodologies, we have not made such an adjustment; however, there are two results from the discontinuance of CSR payments that we considered in adding this adjustment for the 2019 and 2020 payment methodology. First, there are a significant percentage of enrollees with incomes below 200 percent of the FPL in states without BHPs that have chosen to enroll in bronze-level QHPs, despite the availability of CSRs if they had chosen to enroll in a silver-level QHP (about 13 percent in 2018). Second, the discontinuance of the CSR payments

and the subsequent increases to silver-level QHP premiums in 2018 led to a larger difference between the bronze-level and silver-level QHP premiums in many states (from a difference of about 17 percent in 2017 to about 33 percent in 2018). As a result, the likelihood that enrollees eligible for CSRs who enrolled in bronze-level plans would pay \$0 in premium increased (and thus the full value of the PTC they were eligible for would not be paid), and the average difference between the bronze-level premium and the full value of the PTC likely increased. In addition, the percentage of enrollees eligible for CSRs enrolled in bronze-level QHPs also increased from 2017 to 2018 (from 11 percent to 13 percent), and we believe this is likely due to the availability of QHPs that effectively had \$0 in premium due to the PTC for which individuals qualified. Therefore, we are proposing to make an adjustment for enrollees selecting bronze-level QHPs in this methodology.

In addition, we are also considering whether or not to continue to provide states the option to develop a protocol for a retrospective adjustment to the

PHF as we did in previous payment methodologies. We believe that continuing to provide this option is appropriate and likely to improve the accuracy of the final payments.

We also are considering whether or not to require the use of the program year premiums to develop the federal BHP payment rates, rather than allow the choice between the program year premiums and the prior year premiums trended forward. We believe that the payment rates can still be developed accurately using either the prior year QHP premiums or the current program year premiums and that it is appropriate to continue to provide the states the option.

Many of the factors proposed in this notice are specified in statute; therefore, we are limited in the alternative approaches we could consider. One area in which we previously had and still have a choice is in selecting the data sources used to determine the factors included in the proposed methodology. Except for state-specific RPs and enrollment data, we propose using national rather than state-specific data. This is due to the lack of currently

available state-specific data needed to develop the majority of the factors included in the proposed methodology. We believe the national data will produce sufficiently accurate determinations of payment rates. In addition, we believe that this approach will be less burdensome on states. In many cases, using state-specific data would necessitate additional requirements on the states to collect, validate, and report data to CMS. By using national data, we are able to collect data from other sources and limit the burden placed on the states. For RPs and enrollment data, we propose using state-specific data rather than national data as we believe state-specific data will produce more accurate determinations than national averages.

We request public comment on these alternative approaches.

*E. Accounting Statement and Table*

In accordance with OMB Circular A-4, Table 4 depicts an accounting statement summarizing the assessment of the benefits, costs, and transfers associated with this proposed payment methodology.

TABLE 4—ACCOUNT STATEMENT CHANGES TO FEDERAL PAYMENTS FOR THE BASIC HEALTH PROGRAM FOR 2019 AND 2020

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Transfers: Annualized/Monetized (\$million/year) .....	150.0 150.0	2019 2019	7 3	2019–2020 2019–2020
From Whom to Whom .....	From the States Operating BHPs to the Federal Government.			

*F. Reducing Regulation and Controlling Regulatory Costs*

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than *de minimis* costs, and thus is not a regulatory action for the purposes of E.O. 13771.

*G. Conclusion*

Overall, federal BHP payments are expected to decrease by \$300 million from 2019 through 2020 as a result of the changes to the methodology. The decrease in federal BHP payments is expected to be made up in increased state BHP expenditures, with a potential increase in beneficiary contributions and potential decreases in provider payment rates (including rates to

standard health plans in the BHP) as a result of these changes. The analysis above, together with the remainder of this preamble, provides an RIA.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Dated: February 19, 2019.  
**Seema Verma,**  
*Administrator, Centers for Medicare & Medicaid Services.*

Dated: March 5, 2019.  
**Alex M. Azar,**  
*Secretary, Department of Health and Human Services.*

[FR Doc. 2019-06276 Filed 3-29-19; 11:15 am]

**BILLING CODE 4120-01-P**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 1**

[WT Docket No. 19-38, FCC 19-22]

**Partitioning, Disaggregation, and Leasing of Spectrum**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, the Federal Communications Commission explores how potential changes to partitioning, disaggregation, and leasing rules might close the digital divide and to increase spectrum access by small and rural carriers. The document also satisfies the requirement under the Making Opportunities for Broadband Investment and Limiting Excessive and Needless Obstacles to Wireless Act (MOBILE

NOW Act),<sup>1</sup> which requires that the Commission initiate a rulemaking to consider specific questions related to the partitioning or disaggregation of spectrum licenses and spectrum leasing as a potential means to increase availability of advanced telecommunications services in rural areas and spectrum access by small carriers.

**DATES:** Interested parties may file comments on or before May 2, 2019, and reply comments on or before June 3, 2019.

**ADDRESSES:** You may submit comments, identified by WT Docket No. 19–38, by any of the following methods:

- **Electronic Filers:** Comments may be filed electronically using the internet by accessing the Commission's Electronic Comment Filing System (ECFS): <http://fjallfoss.fcc.gov/ecfs2/>. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).

- **Paper Filers:** Parties who choose to file by paper must file an original and one copy of each filing. Generally if more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Commenters are only required to file copies in GN Docket No. 13–111.

- Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

**People with Disabilities:** To request materials in accessible formats for people with disabilities (Braille, large

print, electronic files, audio format), send an email to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

**FOR FURTHER INFORMATION CONTACT:**

Anna Gentry, [Anna.Gentry@fcc.gov](mailto:Anna.Gentry@fcc.gov), of the Wireless Telecommunications Bureau, Mobility Division, (202) 418–2887. For additional information concerning the PRA information collection requirements contained in this document, contact Cathy Williams at (202) 418–2918 or send an email to [PRA@fcc.gov](mailto:PRA@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM) in WT Docket No. 19–38, FCC 19–22, released on March 15, 2019. The complete text of the NPRM is available for viewing via the Commission's ECFS website by entering the docket number, WT Docket No. 19–38. The complete text of the NPRM is also available for public inspection and copying from 8:00 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW, Room CY–B402, Washington, DC 20554, telephone 202–488–5300, fax 202–488–5563.

This proceeding shall continue to be treated as a “permit-but-disclose” proceeding in accordance with the Commission's *ex parte* rules (47 CFR 1.1200 *et seq.*). Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to

be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

### I. Notice of Proposed Rulemaking

**Rulemaking Requirement.** Section 616 of the MOBILE NOW Act requires that, within a year of its enactment, the Commission must “initiate a rulemaking proceeding to assess whether to establish a program, or modify existing programs, under which a licensee that receives a license for exclusive use of spectrum in a specific geographic area under Section 301 of the Communications Act of 1934 (47 U.S.C. 301) may partition or disaggregate the license by sale or long-term lease.”<sup>2</sup> The purpose of any such new or modified program for partitioning and disaggregation would be to provide services consistent with the license and make unused spectrum available to “(I) an unaffiliated small carrier; or (II) an unaffiliated carrier to serve a rural area.”<sup>3</sup> Section 616 conditions the adoption of a new or modified program on the Commission making a finding that it would “promote (i) the availability of advanced telecommunications services in rural areas; or (ii) spectrum availability for covered small carriers.”<sup>4</sup>

**Considerations.** Section 616 requires the Commission to consider four key questions in conducting the rulemaking. First, the Commission must examine whether reduced performance requirements with respect to the spectrum obtained through the program would facilitate deployment of advanced wireless services in rural areas.<sup>5</sup> Second, the rulemaking must explore what conditions may be needed on transfers of spectrum under the program to allow covered small carriers to build out spectrum obtained under the program in a reasonable period of

<sup>2</sup> *Id.* § 616(b)(1).

<sup>3</sup> *Id.* § 616(b)(1)(A).

<sup>4</sup> *Id.* § 616(b)(1)(B).

<sup>5</sup> *Id.* § 616(b)(2)(A).

<sup>1</sup> MOBILE NOW Act, Public Law 115–141, Division P, Title VI, § 601 *et seq.* (2018). The MOBILE NOW Act became law on March 23, 2018.

time.<sup>6</sup> Third, the Commission must consider whether certain incentives may be appropriate to encourage licensees to lease or sell spectrum, including (i) extending the term of a license; or (ii) modifying the performance requirements of the license relating to the leased or sold spectrum.<sup>7</sup> Section 616 provides, however, that the Commission may offer incentives or reduced performance requirements only if it finds that doing so would be likely to result in increased availability of advanced telecommunications services in a rural area.<sup>8</sup> Additionally, if a party fails to meet any buildout requirements set by the Commission for any spectrum sold or leased under a new or modified partitioning and disaggregation program, “the right to the spectrum shall be forfeited to the Commission unless the Commission finds that there is good cause for the failure of the party.”<sup>9</sup> Finally, the Commission must evaluate the administrative feasibility of those or any other incentives the Commission might consider that further the goals of the rulemaking requirement.<sup>10</sup>

*Definitions.* In establishing its dual goals of making spectrum available to small carriers and promoting the availability of advanced telecommunications services in rural areas, Section 616 defines two key terms. First, the term “covered small carrier” is defined as a carrier<sup>11</sup> that “(A) has not more than 1,500 employees (as determined under section 121.106 of title 13, Code of Federal Regulations, or any successor thereto); and (B) offers services using the facilities of the carrier.”<sup>12</sup> Second, Section 616 defines the term “rural area” as any area other than “(A) a city, town, or incorporated area that has a population of more than 20,000 inhabitants; or (B) any urbanized area contiguous and adjacent to a city or town that has a population of more than 50,000 inhabitants.”<sup>13</sup> As a result, these definitions will apply to any use of the terms “covered small carrier” or “rural area” in this *NPRM*, notwithstanding

any definitions of these terms in other Commission proceedings that may differ from those described by Section 616.<sup>14</sup>

The Commission’s existing partitioning, disaggregation, and leasing rules are designed to facilitate spectrum access and encourage secondary market transactions that will lead to efficient use of spectrum. The *NPRM* seeks comment on whether to establish a program, or modify existing programs, for the partitioning, disaggregation, and leasing of licenses. The *NPRM* also seeks comment on what, if any, changes would promote the availability of advanced telecommunications services in rural areas or spectrum availability for covered small carriers—such as allowing additional time to meet performance obligations under certain circumstances. The *NPRM* also asks commenters to address three considerations set forth in Section 616, including addressing the administrative feasibility of each consideration; they are: (1) Whether reduced performance requirements applicable to partitioned or disaggregated licenses would promote the availability of advanced telecommunications services in rural areas or spectrum availability for covered small carriers; (2) what conditions may be needed to eliminate impediments to transfers of spectrum to covered small carriers to allow them to build out in a reasonable period of time; and (3) what incentives may encourage licensees to lease or sell spectrum to covered small carriers or unaffiliated carriers that will serve rural areas. The *NPRM* seeks to develop a record on the success of the Commission’s existing rules and therefore seek comment on whether further Commission action would likely promote the availability of advanced telecommunications services in rural areas and facilitate access to spectrum by covered small carriers.

*Reduced Performance Requirements in Rural Areas.* The *NPRM* seeks comment on whether reduced performance requirements for partitioned or disaggregated licenses would facilitate the deployment of advanced telecommunications services in rural areas. The Commission’s rules permit parties to a partition or disaggregation to agree either to share the responsibility for meeting performance requirements or to satisfy

the requirements individually. The *NPRM* seeks comment on potential modifications to these requirements that may be likely to increase service to rural areas, and on how to ensure that reduced performance requirements do not lead to reduced service in rural areas. The *NPRM* seeks comment on, for example, extending by one year a receiving party’s construction deadline for a partitioned or disaggregated license when (i) the receiving party is a rural carrier or is acquiring spectrum that includes “rural areas,” as defined by Section 616, and (ii) the receiving party elects to meet the construction requirement independently for its partitioned or disaggregated license area. The *NPRM* seeks comment on various aspects of implementing such an approach, or any other approach that commenters advocate.

The *NPRM* asks commenters advocating for these specific approaches, or for other approaches involving reduced performance requirements, to discuss how they would be implemented, including how and when they would take effect, to whom they would apply, and any specific conditions that should apply. Commenters should also describe in detail how any such implementation would serve to promote the availability of advanced telecommunications services in rural areas. Further, in light of Section 616’s requirement that the Commission consider the administrative feasibility of implementing reduced performance requirements, commenters should discuss the costs and benefits of any proposed implementation.

*Conditions on Transfers of Spectrum to Covered Small Carriers.* As a threshold matter, the MOBILE NOW Act directs the Commission to focus on programs that would promote spectrum availability for “covered small carriers,” a term that encompasses only common carriers.<sup>15</sup> While the *NPRM* seeks comment below on issues relating to “covered small carriers,” as required, the Commission also seeks comment on whether it should consider applying any rule revisions to an expanded class of licensees beyond those Congress requires the Commission to consider. The *NPRM* also seeks comment on what conditions may be needed on transfers of spectrum to allow covered small carriers to build out in a reasonable period. The *NPRM* asks whether there are procedural barriers to partitioning or disaggregation that limit the utility of those programs for covered small carriers, and if so, the nature of those barriers and the types of entities that are

<sup>6</sup> MOBILE NOW Act, § 616(b)(2)(B).

<sup>7</sup> *Id.* § 616(b)(2)(C).

<sup>8</sup> *Id.* § 616(b)(3).

<sup>9</sup> *Id.* § 616(b)(3).

<sup>10</sup> *Id.* § 616(b)(2)(D).

<sup>11</sup> Section 616 directs the Commission to use the definition of “carrier” contained in section 3 of the Communications Act of 1934, which defines a carrier as “any person engaged as a common carrier for hire, in interstate or foreign communication by wire or radio or interstate or foreign radio transmission of energy . . . but a person engaged in radio broadcasting shall not, insofar as such person is so engaged, be deemed a common carrier.” 47 U.S.C. 153 (11).

<sup>12</sup> MOBILE NOW Act, § 616(a)(1).

<sup>13</sup> *Id.* § 616(a)(2).

<sup>14</sup> For example, in many proceedings, the Commission has defined a “rural” county or census block as one with a population density of less than 100 people per square mile. *See, e.g., Facilitating the Provision of Spectrum-Based Services to Rural Areas and Promoting Opportunities for Rural Telephone Companies To Provide Spectrum-Based Services*, Report and Order and Further Notice of Proposed Rulemaking, 19 FCC Rcd 19078, 19086–88, paragraphs. 10 through 12 (2004).

<sup>15</sup> *See* 47 U.S.C. 153(11).

currently foreclosed. In addition to procedural barriers to partitioning and disaggregation, the *NPRM* seeks comment on whether there are substantive barriers with respect to covered small carriers' ability to satisfy performance requirements applicable to the partitioned or disaggregated spectrum, and whether reduced construction obligations or extended performance deadlines could increase the number of covered small carriers that are willing and able to obtain spectrum through partitioning, disaggregation, or lease arrangements.

The *NPRM* seeks comment on these and any other relevant considerations regarding special conditions for covered small carriers that obtain access to spectrum through partition or disaggregation. Commenters should discuss in detail both the necessity and the likelihood of any such conditions resulting in increased spectrum availability for covered small carriers. Further, in light of the Section 616 requirement that the Commission consider the administrative feasibility of special conditions for covered small carriers, commenters should also discuss the costs and benefits of any conditions they advocate.

*Incentives to Encourage Lease or Sale.* The *NPRM* seeks comment on what, if any, incentives might be appropriate to encourage licensees to lease or sell spectrum to covered small carriers or unaffiliated carriers that will serve rural areas, including license term extensions or modified performance requirements. The *NPRM* seeks comment on whether the Commission's existing secondary markets rules are sufficiently flexible to provide adequate incentives for licensees to sell or lease their spectrum rights to covered small carriers or unaffiliated carriers that seek to provide service to rural areas. The *NPRM* asks commenters to discuss the effectiveness of existing benefits of sale or lease, and whether further incentives would be likely to encourage licensees to lease or sell spectrum. For example, the *NPRM* seeks comment on whether and how modified performance requirements or longer license terms might encourage more licensees to sell or lease their spectrum rights. The Commission asks commenters to discuss the incremental benefits of increasing the number of spectrum sales or leases relative to the potential collateral effects that such incentives may have. For example, while reduced buildout requirements may increase the number of licensees willing to lease spectrum, it may also decrease deployment of advanced wireless services in those license areas as a result of the reduced performance

requirements. The *NPRM* therefore seeks comment on the specific costs and benefits of any incentives that commenters advocate and the relative weight the Commission should apply in evaluating whether those incentives would be likely to result in increased availability of advanced telecommunications services in rural areas.

The *NPRM* also seeks comment on whether allowing spectrum "reaggregation" for spectrum that has been partitioned or disaggregated on the secondary market—up to the size of the original market area—would increase the incentives of parties to lease or sell spectrum in the first place, and thus ultimately meet the dual goals of increasing the availability of advanced telecommunications services in rural areas and facilitating access to spectrum by covered small carriers. Under the Commission's current rules, while licensees may partition and disaggregate their licenses through spectrum transactions, there is no provision for reaggregating spectrum, even when the partitioned or disaggregated portions of an original market area are acquired by a single entity. Holding multiple licenses for what was once a single license may impose certain regulatory and administrative burdens on licensees, including construction requirements, renewal showings, continuous service requirements, and the need to maintain up-to-date information in ULS. In the context of other proceedings, some parties have asked the Commission to allow reaggregation of spectrum to ease these burdens.<sup>16</sup> The *NPRM* seeks comment on the relationship between reducing these burdens and incentivizing spectrum transactions.

If commenters advocate for incentives such as modified performance requirements, longer license terms, spectrum reaggregation, or another incentive, the Commission directs them to describe in detail how the incentive would likely increase the availability of advanced telecommunications services in rural areas or facilitate access to spectrum by covered small carriers. Further, in light of the Section 616 requirement that the Commission consider the administrative feasibility of providing incentives to lease or sell spectrum, commenters should also discuss the costs and benefits of any incentives they advocate.

<sup>16</sup> See, e.g., Sprint Comments, WT Docket No. 10–112, at 19–20 (filed Aug. 6, 2010); AT&T Reply Comments, WT Docket No. 10–112, at 12 (filed Aug. 23, 2010).

## II. Procedural Matters

### *Initial Regulatory Flexibility Act Analysis*

As required by the Regulatory Flexibility Act of 1980 (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules proposed in this document. We request written public comment on the IRFA. Comments must be filed in accordance with the same deadlines as comments filed in response to the *NPRM* as set forth on the first page of this document, and have a separate and distinct heading designating them as responses to the IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of the *NPRM*, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

### *Initial Paperwork Reduction Act Analysis*

The *NPRM* contains proposed new information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and OMB to comment on the information collection requirements contained in this document, as required by PRA. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might "further reduce the information collection burden for small business concerns with fewer than 25 employees."

Federal Communications Commission.

**Katura Jackson,**

*Federal Register Liaison Officer, Office of the Secretary.*

[FR Doc. 2019–06348 Filed 4–1–19; 8:45 am]

BILLING CODE 6712–01–P

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## OFFICE OF PERSONNEL MANAGEMENT

### 48 CFR Parts 1603 and 1652

RIN 3206–AN56

### Federal Employees Health Benefits Acquisition Regulations: Self Plus One and Contract Matrix Update

**AGENCY:** Office of Personnel Management.

**ACTION:** Proposed rule.

**SUMMARY:** The Office of Personnel Management (OPM) is issuing this

proposed rule to update its regulations concerning “self plus one” and the contract matrix. OPM is updating the Federal Employees Health Benefits Acquisition Regulations (FEHBAR) to include a recently added enrollment type called “self plus one” to the carrier advertising instructions and also provides notice to interested stakeholders that we are updating and clarifying the contract clause matrix.

**DATES:** OPM must receive comments by May 2, 2019.

**ADDRESSES:** You may submit comments identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

- *Federal Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

**FOR FURTHER INFORMATION CONTACT:** Michael W. Kaszynski, Senior Policy Analyst, at [Michael.Kaszynski@opm.gov](mailto:Michael.Kaszynski@opm.gov) or 202–606–1994.

**SUPPLEMENTARY INFORMATION:** This proposed regulation amends the FEHBAR to list a “self plus one” enrollment type in the carrier advertising instructions so that carriers will be required to list all current enrollment types when advertising their health plans enrollment codes and premium rates to enrollees. This change is a technical correction and does not alter current FEHB family member eligibility guidelines.

This proposed regulation also provides notice to interested stakeholders that we are updating and clarifying the contract clause matrix. Annually, OPM determines which FAR and FEHBAR contract clauses are applicable to FEHB carrier contracts and we include the appropriate clauses in the carrier contracts. We also publish clauses and clause headings in the FEHBAR in order to give the clauses legal regulatory authority. This gives new carriers joining the FEHB Program the benefit of seeing OPM’s required clauses in regulation for consideration prior to submitting an application for participation in the FEHB Program. This proposed regulation brings the contract clause matrix in line with the current Federal Acquisition Regulations (FAR) and FEHBAR contract clauses used in

all Federal Employees Health Benefits (FEHB) Program carrier contracts.

Section 706 of the Bipartisan Budget Act of 2013 amended chapter 89 of title 5 United States Code (U.S.C) by adding a self plus one enrollment type for Federal employees and annuitants under the FEHB Program. The self plus one enrollment type became available during the 2015 Open Season for the 2016 plan year and was codified in a final rule at <https://www.federalregister.gov/documents/2015/09/17/2015-23348/federal-employees-health-benefits-program-self-plus-one-enrollment-type>. A self plus one enrollment covers the enrollee and one eligible family member, designated by the enrollee. Eligible family members under a self plus one enrollment include a spouse or eligible child as set forth in § 890.302 of title 5 CFR.

OPM manages the FEHB program which is executed with contractors managing and providing the FEHB benefits to government employees. This rule proposes to update the Federal Employee Health Benefits Acquisition Regulations (FEHBAR) to implement the “self plus one” program via FEHB contracts, and make the FEHB contract clauses consistent with current FAR and FEHBAR clause requirements. Specifically, the regulation amends the FEHBAR at 48 CFR part 1603 to list a self plus one enrollment type in the advertising instructions. OPM considers this change a technical correction as it does not change the operational requirements of the FEHB program and does not alter current FEHB family member eligibility guidelines.

This regulation also provides notice to interested stakeholders that we are updating the contract clause matrix at 48 CFR 1652.370. This will bring the matrix in line with current FAR and FEHBAR contract clauses used in all FEHB Program carrier contracts. The matrix at FEHBAR section 1652.370 lists the FAR and FEHBAR clauses to be used in contracts based on cost analysis and contracts based on a combination of cost and price analysis. Carriers must comply with all matrix clauses during their participation in the FEHB Program. Certain contract clauses are mandatory for FEHB contracts and others are used only when made applicable by pertinent sections of the FAR or FEHBAR. This regulation updates the matrix to include all current contract clauses.

#### Regulatory Impact Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 also emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a significant regulatory action under E.O. 12866.

#### Reducing Regulation and Controlling Regulatory Costs

This proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866.

#### Regulatory Flexibility Act

The Office of Personnel Management certifies that this rule will not have a significant economic impact on a substantial number of small entities.

#### Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of state, local, or tribal governments.

#### Civil Justice Reform

This regulation meets the applicable standard set forth in Executive Order 12988.

#### Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### Congressional Review Act

This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of no agency parties and, accordingly, is not a “rule” as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

#### Paperwork Reduction Act

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a

penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number.

This rule involves an OMB approved collection of information subject to the PRA Health Benefits Election, SF 2809, OMB no. 3206–0160. The public reporting burden for this collection is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total burden hour estimate for this form is 9,000 hours. The systems of record notice for this collection is: OPM SORN GOVT–1 General Personnel Records and OPM SORN CENTRAL–18–Federal Employees Health Benefits Program Claims Data Warehouse.

**List of Subjects in 48 CFR Parts 1603 and 1652**

Government employees, Government procurement, Health insurance, Reporting and recordkeeping requirements.

Office of Personnel Management.  
**Alexys Stanley,**  
*Regulatory Affairs Analyst.*

Accordingly, OPM is proposing to amend title 48, Code of Federal

Regulations, parts 1603 and 1652 as follows:

**PART 1603—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST**

■ 1. The authority citation for part 1603 continues to read as follows:

**Authority:** 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

■ 2. Section 1603.7002 paragraph (e) is revised to read as follows:

**1603.7002 Additional guidelines.**

\* \* \* \* \*

(e) Not give instructions on enrollment. Statements on enrollment procedures, requirements, or eligibility shall be limited to those such as: To sign up, fill out a Health Benefits Election Form (Standard Form 2809) from your personnel office indicating the enrollment you want or use your agency’s electronic enrollment system:

The enrollment codes for (plan’s name) are:

Self Only \_ Enrollment Code \_  
 Self Plus One \_ Enrollment Code \_  
 Self and Family \_ Enrollment Code \_

The form must then be returned to your personnel office before the (date) deadline. Your (plan’s name) coverage will begin the first pay period in January, (year). If you are a retired Federal employee and need forms, contact the Office of Personnel Management, 1900 E Street NW, Attn:

Retirement Benefits Branch,  
 Washington, DC 20415 or visit  
[www.opm.gov/forms](http://www.opm.gov/forms).

**PART 1652—CONTRACT CLAUSES**

■ 3. The authority citation for part 1652 continues to read as follows:

**Authority:** 5 U.S.C. 8913; 40 U.S.C. 486(c); 48 CFR 1.301.

■ 4. Section 1652.370 is revised as follows

**1652.370 Use of the matrix.**

(a) The matrix in this section lists the FAR and FEHBP clauses to be used with contracts based on cost analysis and contracts based on a combination of cost and price analysis. Carriers shall submit initial applications and requests for renewals on the basis that the new contract or contract renewal will include the clauses indicated.

(b) Certain contract clauses are mandatory for FEHBP contracts. Other clauses are to be used only when made applicable by pertinent sections of the FAR or FEHBP. An “M” in the “Use Status” column indicates that the clause is mandatory. An “A” indicates that the clause is to be used only when the applicable conditions are met.

(c) Clauses are incorporated in the contract either in full text or by reference. If the full text is to be used, the matrix indicates a “T”. If the clause is incorporated by reference, the matrix indicates an “R”.

**FEHBP CLAUSE MATRIX**

Clause	Title	Use status	Use with experience rated contracts	Use with community rate contracts
FAR 52.202–1	Definitions	M	T	T
FAR 52.203–3	Gratuities	M	T	T
FAR 52.203–5	Covenant Against Contingent Fees	M	T	T
FAR 52.203–7	Anti-Kickback Procedures	M	T	T
FAR 52.203–12	Limitation on Payments to Influence Certain Federal Transactions.	M	T	T
FAR 52.203–13	Contractor Code of Business Ethics and Conduct	M	T	T
FAR 52.203–17	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights.	M	T	T
FAR 52.203–19	Prohibition Requiring Internal Confidentiality Agreements or Statements.	M	T	T
FAR 52.204–7	System For Rewards Management	M	T	T
FAR 52.204–9	Personnel Identity Verification of Contractor Personnel	M	T	T
FAR 52.204–21	Basic Safeguarding of Contractor Information Systems	M	T	T
FAR 52.209–9	Updates of Publically Available Information Regarding Responsibility Matters.	M	T	T
1652.203–70	Misleading, Deceptive, or Unfair Advertising	M	T	T
1652.204–70	Contractor Records Retention	M	T	T
1652.204–71	Coordination of Benefits	M	T	T
1652.204–72	Filing Health Benefit Claims/Court Review of Disputed Claims.	M	T	T
1652.204–73	Taxpayer Identification Number	M	T	T
1652.204–74	Large Provider Agreements	M	T	

## FEHBP CLAUSE MATRIX—Continued

Clause	Title	Use status	Use with experience rated contracts	Use with community rate contracts
FAR 52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment.	M	T	T
FAR 52.215-2	Audit & Records—Negotiation	M	T	T
FAR 52.215-10	Price Reduction for Defective Cost or Pricing Data	M	T	
FAR 52.215-12	Subcontractor Certified Cost or Pricing Data	M	T	
FAR 52.215-15	Pension Adjustments and Asset Reversions	M	T	
FAR 52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions.	M	T	
1652.215-70	Rate Reduction for Defective Pricing or Defective Cost or Pricing Data.	M	T	T
1652.215-71	Investment Income	M	T	
1652.216-70	Accounting and Price Adjustment	M		T
1652.216-71	Accounting and Allowable Cost	M	T	
FAR 52.219-8	Utilization of Small Business Concerns	M	T	T
FAR 52.222-1	Notice to the Government of Labor Disputes	M	T	T
FAR 52.222-3	Convict Labor	M	T	T
FAR 52.222-4	Contract Work Hours and Safety Standards Act—Overtime Compensation.	M	T	T
FAR 52.222-21	Prohibition of Segregated Facilities	M	T	T
FAR 52.222-26	Equal Opportunity	M	T	T
FAR 52.222-29	Notification of Visa Denial	A	T	T
FAR 52.222-35	Equal Opportunity for Veterans	M	T	T
FAR 52.222-36	Equal Opportunity for Workers With Disabilities	M	T	T
FAR 52.222-37	Employment Reports on Veterans	M	T	T
FAR 52.222-50	Combating Trafficking in Persons	M	T	T
FAR 52.222.54	Employment Eligibility Verification	M	T	T
1652.222-70	Notice of Significant Events	M	T	T
FAR 52.223-6	Drug-Free Workplace	A	T	T
FAR 52.223-18	Encouraging Contractor Policies to Ban Text Messaging While Driving.	M	T	T
1652.224-70	Confidentiality of Records	M	T	T
FAR 52.227-1	Authorization and Consent	M	T	T
FAR 52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement.	M	T	T
FAR 52.229-4	Federal, State and Local Taxes (State and local Adjustments).	M	T	T
1652.229-70	Taxes—Foreign Negotiated Benefits Contracts	A	T	T
FAR 52.232-8	Discounts for Prompt Payment	M	T	T
FAR 52.232-17	Interest	M	T	T
FAR 52.232-23	Assignment of Claims	A	T	T
FAR 52.232-33	Payment by Electronic Funds Transfer—System for Awards Management.	M	T	T
1652.232-70	Payments—Community-Rated Contracts	A		T
1652.232-71	Payments—Experience-Rated Contracts	A	T	
1652.232-72	Non-Commingling of FEHBP Funds	M	T	
1652.232-73	Approval for Assignment of Claims	M	T	T
FAR 52.233-1	Disputes	M	T	T
FAR 52.233-4	Applicable Law for Breach of Contract Claim	M	T	T
FAR 52.239-1	Privacy or Security Safeguards	M	T	T
FAR 52.242-1	Notice of Intent to Disallow Costs	M	T	
FAR 52.242-3	Penalties for Unallowable Costs	M	T	
FAR 52.242-13	Bankruptcy	M	T	T
1652.243-70	Changes—Negotiated Benefits Contracts	M	T	T
FAR 52.244-5	Competition in Subcontracting	M	T	
FAR 52.244-6	Subcontracts for Commercial Items	M	T	
1652.244-70	Subcontracts	M	T	
1652.245-70	Government Property (Negotiated Benefits Contracts)	M	T	T
FAR 52.246-25	Limitation of Liability—Services	M	T	
1652.246-70	FEHB Inspection	M	T	T
FAR 52.247-63	Preference for U.S.-Flag Air Carriers	M	T	T
1652.249-70	Renewal and Withdrawal of Approval	M	T	T
1652.249-71	FEHBP Termination for Convenience of the Government—Negotiated Benefits Contracts.	M	T	T
1652.249-72	FEHBP Termination for Default—Negotiated Benefits Contracts.	M	T	T
FAR 52.251-1	Government Supply Sources	A	T	
FAR 52.252-4	Alterations in Contract	A	T	T
FAR 52.252-6	Authorized Deviations in Clauses	M	T	T

[FR Doc. 2019-06223 Filed 4-1-19; 8:45 am]

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**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 622**

RIN 0648-B111

**Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic; Amendment 13**

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

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Gulf of Mexico (Gulf) and South Atlantic Fishery Management Councils (Councils) have submitted Amendment 13 to the Fishery Management Plan for Spiny Lobster in the Gulf of Mexico and South Atlantic (FMP), for review, approval, and implementation by NMFS. Amendment 13 would modify the applicable Federal regulations for the harvest of spiny lobster in the exclusive economic zone (EEZ) off Florida to be compatible with Florida regulations, and would re-establish a procedure for an enhanced cooperative management with Florida. The purpose of Amendment 13 is to more effectively manage and enforce the harvest of spiny lobster.

**DATES:** Written comments on Amendment 13 must be received on or before June 3, 2019.

**ADDRESSES:** You may submit comments on Amendment 13, identified by “NOAA-NMFS-2018-0088” by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to [www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0088](http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0088), click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Susan Gerhart, Southeast Regional Office, NMFS, 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](http://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 the required fields if you wish to remain anonymous).

Electronic copies of Amendment 13 may be obtained from the Southeast Regional Office website at <https://www.fisheries.noaa.gov/action/amendment-13-modifications-spiny-lobster-gear-requirements-and-cooperative-management>. Amendment 13 includes an environmental assessment, a fishery impact statement, a Regulatory Flexibility Act (RFA) analysis, and a regulatory impact review.

**FOR FURTHER INFORMATION CONTACT:** Susan Gerhart, Southeast Regional Office, NMFS, telephone: 727-824-5305; email: [Susan.Gerhart@noaa.gov](mailto:Susan.Gerhart@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each regional fishery management council to submit any FMP or amendment to NMFS for review and approval, partial approval, or disapproval. The Magnuson-Stevens Act also requires that NMFS, upon receiving an FMP or amendment, publish an announcement in the **Federal Register** notifying the public that the FMP or amendment is available for review and comment.

The FMP being revised by Amendment 13 was prepared by the Councils and implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Act.

**Background**

In the Gulf and South Atlantic, spiny lobster are harvested primarily off the coast of Florida. The original FMP, implemented in 1982, largely complemented Florida’s management regime and provided protection for the fishery throughout its range in the Gulf and the South Atlantic (47 FR 29202; July 2, 1982). The FMP adopted many of the management measures implemented by Florida to achieve its conservation and management objectives and effectively coordinate management with Florida. However, it was difficult to keep Federal regulations consistent with changing state regulations because Florida can adjust its management measures more quickly than the Councils and NMFS can change Federal regulations. As a result,

NMFS and the Councils developed Amendment 2 to the FMP (54 FR 48059; November 20, 1989), which established a procedure to allow Florida to directly propose to NMFS its state spiny lobster regulations for subsequent implementation in the EEZ off Florida. That procedure was developed to provide a more timely regulatory mechanism to implement compatible regulations and a more formal process for state and Federal coordination.

In 2017, representatives from the Florida Fish and Wildlife Conservation Commission contacted the NMFS Southeast Regional Office requesting that Federal regulations be aligned with Florida state regulations concerning requirements for spiny lobster bulley net gear and for daily commercial possession limits of spiny lobster harvested by bulley net or diving. However, NMFS determined that the previously established cooperative management procedure for the spiny lobster protocol established in Amendment 2 was removed in Amendment 10 to the FMP (76 FR 75488; December 2, 2011). Consequently, there is no procedure to implement regulations proposed by Florida without a plan amendment or framework to the FMP developed by the Council. These more lengthy processes are inconsistent with promoting compatible regulations for the fishery off Florida.

**Actions Contained in Amendment 13**

Amendment 13 includes measures to modify the Federal regulations for the harvest of spiny lobster that apply in the EEZ off Florida to be compatible with Florida regulations concerning bulley net gear requirements and commercial daily possession limits when using bulley nets or diving. These changes include updating the incorporations by reference to the Florida regulations, as appropriate. Amendment 13 would also re-establish a procedure for an enhanced cooperative management system to provide the state of Florida with a mechanism to propose spiny lobster regulations directly to NMFS for implementation, without a full amendment or framework action to the FMP.

**Florida Bulley Net Permit and Gear Marking Requirements and Prohibitions**

In 2017, Florida implemented a bulley net permit, gear marking requirements, and gear prohibitions. There is limited information as to how much spiny lobster bulley netting effort occurs in the Federal waters off Florida. However, stakeholders have expressed concerns that spiny lobster bulley net vessels are

used to disguise unlawful activities and that there are growing conflicts between recreational bully netters and commercial bully netters. Amendment 13 proposes to align Federal and Florida regulations to address these concerns. In addition, consistency between Florida and Federal regulations is expected to improve enforcement and reduce potential confusion among fishers.

Amendment 13 would require commercial bully net vessels in the EEZ off Florida to have a bully net permit from Florida, require that the vessel be marked with the harvester's Florida bully net permit number using reflective paint or other reflective material, prohibit commercial bully net vessels from having trap pullers onboard, and prohibit the simultaneous possession of a bully net and any underwater breathing apparatus (not including dive masks or snorkels) onboard a vessel used to harvest or transport spiny lobster for commercial purposes.

#### *Commercial Spiny Lobster Bully Net and Diving Trip Limits*

The Federal regulations do not include an express commercial daily vessel harvest and possession limit for spiny lobster harvested by bully net or diving. However, current Federal regulations require commercial spiny lobster harvesters in the EEZ off Florida to have the licenses and certificates specified to be a "commercial harvester," as defined in Florida's regulations as of 2008. The 2008 version of "commercial harvester" included a person holding the appropriate licenses and certificates for traps and dive gear.

Amendment 13 would incorporate by reference the most recent Florida regulations, which define a commercial harvester as a person who holds a valid saltwater products license with a

restricted species endorsement issued by the Florida Fish and Wildlife Conservation Commission (FWC) and (1) a valid crawfish license or trap number and lobster trap certificates, if traps are used to harvest spiny lobster; (2) a valid commercial dive permit if harvest is by diving; or (3) a valid bully net permit if harvest is by bully net. Under Florida's regulations, commercial harvesters are restricted to the commercial harvest limits when bully net gear or dive gear is used. Therefore, bully net and dive fishermen would be restricted to the state bag limit regardless where the spiny lobster are harvested. However, to make the requirements in the EEZ off Florida more clear, Amendment 13 would add an express commercial vessel limit of 250 spiny lobster per vessel per day for spiny lobster harvested by bully net off all Florida counties and harvested by diving off Broward, Dade, Monroe, Collier, and Lee Counties, Florida.

#### *Establish an Enhanced Cooperative Management Procedure for Federal and Florida State Agencies*

The procedure for the protocol, as last modified in Amendment 2 to the FMP, provided NMFS the flexibility to respond quickly to changes in the spiny lobster fishery by allowing Florida to propose its spiny lobster regulations directly to NMFS for implementation in the EEZ off Florida. The procedure was removed in 2012 when Amendment 10 to the FMP established a new framework procedure (76 FR 75488; December 2, 2011). Without the procedure, Florida cannot propose rules directly to NMFS, limiting the ability to implement consistent regulations in a timely manner.

Amendment 13 would re-establish a procedure for an enhanced cooperative

management system to provide Florida with a mechanism to propose regulations concerning spiny lobster directly to NMFS for implementation.

#### *Proposed Rule for Amendment 13*

A proposed rule that would implement Amendment 13 has been drafted. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable laws. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

#### *Consideration of Public Comments*

The Councils have submitted Amendment 13 for Secretarial review, approval, and implementation. Comments on Amendment 13 must be received by June 3, 2019. Comments received during the respective comment periods, whether specifically directed to Amendment 13 or the proposed rule, will be considered by NMFS in its decision to approve, partially approve, or disapprove Amendment 13. Comments received after the comment periods will not be considered by NMFS in this decision. All comments received by NMFS on Amendment 13 or the proposed rule during their respective comment periods will be addressed in the final rule.

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

Dated: March 25, 2019.

**Jennifer M. Wallace,**

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

[FR Doc. 2019-05969 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-22-P**

# Notices

Federal Register

Vol. 84, No. 63

Tuesday, April 2, 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

### Food Safety and Inspection Service

[Docket No. FSIS-2019-0005]

#### Notice of Request To Renew an Approved Information Collection: Registration Requirements

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to renew the approved information collection regarding business registration requirements. The approval for this information collection will expire on August 31, 2019. FSIS is making no changes to the approved collection.

**DATES:** Submit comments on or before June 3, 2019.

**ADDRESSES:** FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2019-0005. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250-3700; (202) 720-5627.

#### SUPPLEMENTARY INFORMATION:

*Title:* Registration Requirements.  
*OMB Control Number:* 0583-0028.  
*Expiration Date:* 08/31/2019.

*Type of Request:* Renewal of an approved information collection.

*Abstract:* FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS is requesting renewal of the information collection regarding business registration requirements. The approval for this information collection will expire on August 31, 2019. FSIS is making no changes to the approved collection. Provisions of the FMIA (21 U.S.C. 643) and the PPIA (21 U.S.C. 460 (c)) prohibit any person, firm, or corporation from engaging in commerce as a meat or poultry products broker; renderer; animal food manufacturer; wholesaler of livestock or poultry carcasses or parts; or public warehouseman storing such articles in or for commerce; or from engaging in the business of buying, selling, or transporting in commerce, or importing any dead, dying, or disabled or diseased livestock or poultry or parts of the

carcasses of livestock or poultry that died otherwise than by slaughter, unless it has registered its business with FSIS as required by the regulations.

According to the regulations (9 CFR 320.5 and 381.179), parties required to register with FSIS must do so by submitting a form (FSIS Form 5020-1, Registration of Meat and Poultry Handlers) and must provide current and correct information to FSIS, including their name, the address of all locations at which they conduct the business that requires them to register, and all trade or business names under which they conduct these businesses. In addition, parties required to register with FSIS must do so within 90 days after they begin to engage in any of the businesses that require registration. They must also notify FSIS in writing when information on the form changes.

An official establishment that conducts any of these activities does not have to register (9 CFR 320.5(c) and 381.179(c)). An official establishment is a slaughtering, cutting, canning, or other food processing establishment where inspection is maintained under the meat and poultry regulations (9 CFR Subchapters A, D, and E).

FSIS has made the following estimates based upon an information collection assessment:

*Respondents:* Brokers, renderers, animal food manufacturers, wholesalers, public warehousemen, meat and poultry handlers.

*Estimate of Burden:* FSIS estimates that it will take respondents an average of 10 minutes to complete and submit this form to FSIS.

*Estimated Number of Respondents:* 1,200.

*Estimated Number of Annual Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 200 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250-3700; (202) 720-5627.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's

estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

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.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

#### USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United

States under any program or activity conducted by the USDA.

#### How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at [http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:  
**Mail:** U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250-9410.

**Fax:** (202) 690-7442.

**Email:** [program.intake@usda.gov](mailto:program.intake@usda.gov).

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done in Washington, DC.

**Carmen M. Rottenberg,**

*Administrator.*

[FR Doc. 2019-06299 Filed 4-1-19; 8:45 am]

**BILLING CODE 3410-DM-P**

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS-2019-0006]

#### Notice of Request To Revise an Approved Information Collection: Import of Undenatured Inedible Product and Samples for Laboratory Examination, Research, Evaluative Testing, or Trade Show Exhibition

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to revise the approved information collection regarding the importation of undenatured inedible meat and egg products into the United States. The approval for this information collection will expire on September 30, 2019. FSIS is adding to this collection a form for samples taken for laboratory examination, research, evaluative testing, or trade show exhibition. The Agency has increased the burden estimate by 23,263 hours due to updated information and the addition of this form.

**DATES:** Submit comments on or before June 3, 2019.

**ADDRESSES:** FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2019-0006. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202) 720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250-3700; (202) 720-5627.

#### SUPPLEMENTARY INFORMATION:

*Title:* Import of Undenatured Inedible Product and Samples for Laboratory Examination, Research, Evaluative Testing, or Trade Show Exhibition.

*OMB Control Number:* 0583-0161.

*Expiration Date:* 09/30/2019.

*Type of Request:* Revision to an approved information collection.

*Abstract:* FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome,

unadulterated, and properly labeled and packaged.

FSIS is requesting a revision to the approved information collection regarding the importation of undenatured inedible products. FSIS uses the forms in this information collection to identify and keep track of product not subject to FSIS import reinspection requirements. The approval for this information collection will expire on September 30, 2019. FSIS is adding to this collection a form for samples of this product taken for laboratory examination, research, evaluative testing, or trade show exhibition, to ensure this product is not distributed in commerce. The Agency has increased the burden estimate by 23,263 hours due to updated information and the addition of this form.

Undenatured inedible meat and egg products may be imported into the United States if they meet the requirements of FSIS's regulations (9 CFR 325.11(e) and 590.45(d)). Additionally, foreign governments are to petition FSIS for approval to import undenatured inedible egg products into the United States (9 CFR 590.45(d)).

Firms complete FSIS Form 9540-4, "Permit Holder—Importation of Undenatured Inedible Product" for the undenatured inedible product that they are importing into the United States. FSIS uses the information on the Form 9540-4 to keep track of the movement of imported undenatured inedible meat and egg products.

Additionally, meat, poultry, and egg product samples destined for laboratory examination, research, evaluative testing, or trade show exhibition are not subject to FSIS import reinspection requirements. Firms will be required to complete FSIS Form 9540-5, "Notification of Intent to Import Meat, Poultry, Or Egg Products 'Samples for Laboratory Examination, Research, Evaluative Testing or Trade Show Exhibition'" to ensure that samples imported into the United States are not mixed with product that will be sold or distributed in commerce. (9 CFR 327.19, and 381.207, and 590.960).

FSIS has made the following estimates based upon an information collection assessment:

*Respondents:* Importers.

*Estimate of Burden:* FSIS estimates that it will take respondents an average of 115 hours annually to complete and submit these forms to FSIS.

*Estimated Number of Respondents:* 209.

*Estimated Number of Annual Responses per Respondent:* 360.

*Estimated Total Annual Burden on Respondents:* 23,930 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250-3700; (202) 720-5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

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.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and

notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

#### USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

#### How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at [http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\\_combined\\_6\\_8\\_12.pdf](http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf), or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:  
*Mail:* U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250-9410.

*Fax:* (202) 690-7442.

*Email:* [program.intake@usda.gov](mailto:program.intake@usda.gov).

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done in Washington.

**Carmen M. Rottenberg,**  
*Administrator.*

[FR Doc. 2019-06298 Filed 4-1-19; 8:45 am]

BILLING CODE 3410-DM-P

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### Agency Information Collection Activities: Proposed Collection; Comment Request—Federal Claims Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims

**AGENCY:** Food and Nutrition Service, 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 proposed information collections. This

revision of an existing collection announces the intent of the Food and Nutrition Service to revise and continue the requirements associated with initiating and conducting Federal collection actions against households with delinquent Supplemental Nutrition Assistance Program (SNAP) recipient debts.

**DATES:** Written comments must be submitted on or before June 3, 2019 to be assured consideration.

**ADDRESSES:** Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate, automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Jane Duffield, Chief, State Administration Branch, Supplemental Nutrition Assistance Program, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 818, Alexandria, Virginia, 22302. Comments may also be submitted via fax to the attention of Jane Duffield at 703-605-0795. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov> and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia 22302, Room 818.

All comments will be summarized and included in the request for Office of Management and Budget approval of the information collection. All comments will become a matter of public record.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of this information collection should be directed to Richard Duckworth at (703) 605-4271.

**SUPPLEMENTARY INFORMATION:**

*Title:* Federal Claims Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims.

*OMB Number:* 0584-0446.

*Form Number:* None.

*Expiration Date:* September 30, 2019.

*Type of Request:* Revision of a currently approved collection.

*Abstract:* Section 13(b) of the Food and Nutrition Act of 2008, as amended (7 U.S.C. 2022(b)), and Supplemental Nutrition Assistance Program (SNAP) regulations at 7 CFR 273.18 require State agencies to refer delinquent debtors for SNAP benefit over-issuance to the U.S. Department of the Treasury for collection. The Debt Collection Improvement Act of 1996 (Pub. L. 104-134), as amended by the Digital Accountability and Transparency Act of 2014 (Pub. L. 113-101), requires these debts to be referred to Treasury for collection when they are 120 days or more delinquent. Through the Treasury Offset Program (TOP), 31 CFR part 285, payments such as Federal income tax refunds, Federal salaries and other Federal payments payable to these delinquent debtors will be offset and the amount applied to the delinquent debt. TOP places a burden on States agencies and/or former SNAP recipients who owe delinquent debts in three areas: (1) 60-day notices from State agencies to debtors that their debt will be referred to TOP; (2) State-level submissions; and (3) automated data processing (ADP). Below, the burden narrative and chart depicts the burden estimates by these three areas and affected public.

**TOP 60-Day Notice Burden**

The burden associated with the information collection involves both the households (debtors) and the State agencies. The TOP 60-day notice notifies the household of the proposed referral to TOP and provides the right for review and appeal. The State agency prepares and mails the notices as well as responds to inquiries and appeals. The household, in turn, receives and reads the notice and may make an inquiry or appeal the impending action. Based on an average of the number of records for claims the States sent to TOP for calendar years 2015, 2016, 2017 and 2018, we estimate that State agencies will produce and send and that households will read 305,020 TOP 60-day notices. We estimate that the households will submit and State agencies will respond to about 21,351 phone and informal inquiries. Households will file and the States will respond to an estimated 1,829 appeals. An additional 3,000 notices will be sent directly from FNS to Federal employees concerning the potential offset of their Federal salary. Historically, 30 percent of these notices will result in a phone inquiry from a household; and approximately 20 notices will result in

a formal appeal to FNS requiring documentation from the State. Thus, the total number of responses for the 60-day notice and household inquiry is 660,340 responses (332,120 household responses + 328,220 State Agency responses) per year resulting in an annual reporting burden of 43,563 hours. The existing burden for activity relating to the 60-day notice is 33,960.80 hours. The net increase of 9,602 hours is due to an increase in the average number of 60-day notices sent to debtors by State agencies between 2014 and 2018.

**TOP State-Level Submissions**

Treasury prescribes specific processes and file formats for FNS to use to send debts to TOP. FNS provides guidance and file formats to State agencies and monitors their compliance with such. State agencies must submit an annual letter to FNS certifying that all of the debts submitted in the past and all debts to be submitted in the upcoming calendar year by the State agency to TOP are valid and legally enforceable in the amount stated. FNS estimates that it will take State agencies a total of 26.5 hours per year for these State submissions. This burden has not changed with this activity. State agencies also report TOP collections on the FNS-209 form, "Status of Claims Against Households." The burden for completing the FNS-209 is covered under OMB number 0584-0594.

**TOP ADP Burden**

The burden for ADP includes weekly file processing, monthly address requests and system maintenance. Weekly and monthly file processing includes requesting addresses to use to send out 60-day notices, adding and maintaining debts in TOP, correcting errors on unprocessable records, and posting weekly collection files. Much of this activity is completed using automation and involves an estimated 1.4 million records annually. FNS estimates that this activity takes 12,374.82 annual reporting and 689 recordkeeping burden hours. This burden has not changed with this activity.

**Summary of Estimated Burden**

The net aggregate change from the existing to the revised annual burden for this entire Information Collection is an increase of 9,602 hours from the previous submission. For the activity relating to the 60-day notice, we are increasing the estimated annual burden for State agencies and households from 33,960.80 hours to 43,563 hours to reflect an increase in the number of notices and the resulting inquiries and

appeals. The State-level submissions portion of the reporting and recordkeeping burden is estimated to require the same number of hours as the currently approved collection, 26.5 hours. The annual ADP portion of this burden package is also estimated to require the same number of hours as the currently approved collection, 12,374.82 reporting and 689 recordkeeping hours. This results in a final total of 56,653 annual burden hours.

**Reporting Burden**

*Affected Public:* Households/Debtors. *Estimated Number of Respondents:* 305,020.

*Estimated Number of Responses per Respondent:* 1.09.  
*Estimated Total Number of Annual Responses:* 332,120.  
*Estimated Hours per Response:* 0.096974.  
*Estimated Total Annual Burden:* 32,206.92 hours.  
*Affected Public:* State and local government.  
*Estimated Number of Respondents:* 53.  
*Estimated Number of Responses per Respondent:* 6,315.92.  
*Estimated Total Number of Annual Responses:* 334,744.

*Estimated Hours per Response:* .07.  
*Estimated Total Annual Burden:* 23,757.40 hours.  
**State Agency Recordkeeping Burden**  
*Affected Public:* State and local government.  
*Estimated Number of Respondents:* 53.  
*Estimated Number of Responses per Respondent:* 52.  
*Estimated Total Number of Annual Responses:* 2,756.  
*Estimated Hours per Response:* .25.  
*Estimated Total Annual Burden:* 689.

**REPORTING AND RECORDKEEPING BURDEN ESTIMATES**

Section of Reg.	Description	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total annual burden hours
Households (Debtors) A. Due-Process Notice Requirements.	Reading State Issued Notice .....	305,020	1.00	305,020	0.08	25,469.17
	Informal Inquiries to State .....	21,351	1.00	21,351	0.25	5,337.75
	Formal Appeals to State .....	1,829	1.00	1,829	0.50	914.50
	Reading FNS issued letter to Federal employees.	3,000	1.00	3,000	0.0835	250.50
	Phone Inquiries and informal appeals for FNS letter.	900	1.00	900	0.25	225.00
	Formal appeals to FNS .....	20	1.00	20	0.5	10.00
	<b>Totals .....</b>		<b>305,020</b>	<b>1.09</b>	<b>332,120</b>	<b>0.0969737</b>
State Agencies A. Due-Process Notice Requirements:	State Notice Production .....	53	5,755.09	305,020	0.02	5,093.83
	Responding to State Phone/informal Inquiries.	53	402.85	21,351	0.25	5,337.75
	Responding to State Formal Appeals .....	53	34.51	1,829	0.50	914.50
	Providing documents for formal appeals to FNS.	53	0.38	20	0.5	10.00
	<b>Totals .....</b>		<b>53</b>	<b>6,315.92</b>	<b>334,744</b>	<b>0.07</b>
B. State Agency Reporting:	Certification Letter .....	1	53	0.50	26.50	1.00
C. TOP Automated Data Processing:	System Compatibility File .....	53	1.00	53	11.50	609.50
	Address File .....	53	8.00	424	1.63	693.07
	Collections File .....	53	8.00	424	6.50	2,756.00
	State Agency Profile .....	53	1.00	53	0.25	13.25
	Testing New System .....	5	1.00	5	7.00	35.00
	Weekly Files .....	53	52.00	2,756	1.50	4,134.00
	Weekly Files—Post TOP Data .....	53	52.00	2,756	1.50	4,134.00
<b>Totals .....</b>		<b>53</b>	<b>6,315.92</b>	<b>334,744</b>	<b>0.07</b>	<b>23,757.40</b>
<b>Overall Reporting Totals .....</b>		<b>305,073</b>	<b>2.19</b>	<b>666,864</b>	<b>0.08</b>	<b>55,964</b>

*State Agency Recordkeeping:* Per 7 CFR 272.1(f), State agencies are required to retain all records associated with the administration of SNAP for no less than 3 years. The burden for the retention of weekly TOP files is displayed below.

**RECORDKEEPING**

Number of recordkeepers	Annual records per record-keeper	Total records per record-keeper	Hours per record	Total recordkeeping burden
53	52	2,756	0.25	689.00

Dated: March 22, 2019.

**Brandon Lipps,**

*Administrator, Food and Nutrition Service.*

[FR Doc. 2019-06318 Filed 4-1-19; 8:45 am]

**BILLING CODE 3410-30-P**

**COMMISSION ON CIVIL RIGHTS**

**Notice of Public Meeting of the Nevada 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 (FACA) that a meeting of the Nevada Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (Pacific Time) Monday, April 22, 2019, the purpose of meeting is for the committee to continue planning for a community forum in Northern Nevada focused on the impact of policing practices on individuals with mental health concerns and veterans.

**DATES:** The meeting will be held on Monday, April 22, 2019 at 1:00 p.m. PT

**ADDRESSES:** Public Call Information:

*Dial:* 855-719-5012

*Conference ID:* 9926088

**FOR FURTHER INFORMATION CONTACT:** Ana Victoria Fortes (DFO) at [afortes@usccr.gov](mailto:afortes@usccr.gov) or (213) 894-3437

**SUPPLEMENTARY INFORMATION:** This meeting is available to the public through the following toll-free call-in number: 855-719-5012, conference ID number: 9926088. Any interested member of the public may call this number and listen to the meeting. 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 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.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S.

Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894-0508, or emailed Ana Victoria Fortes at [afortes@usccr.gov](mailto:afortes@usccr.gov). Persons who desire additional information may contact the Regional Programs Unit at (213) 894-3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at <https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlJAAQ>.

Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

**Agenda**

- I. Welcome
- II. Approval of Minutes for March 19, 2019 Meeting
- III. Continue planning for Community Form in Northern Nevada
- IV. Public Comment
- V. Next Steps

Dated: March 28, 2019.

**David Mussatt,**

*Supervisory Chief, Regional Programs Unit.*

[FR Doc. 2019-06374 Filed 4-1-19; 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 Tuesday, April 2, 2019, at 3:00 p.m. (EST) for the purpose of planning future public meetings on voting rights in the state.

**DATES:** The meeting will be held on Tuesday, April 2, 2019, at 3:00 p.m. (EST).

**FOR FURTHER INFORMATION CONTACT:** Jeff Hinton, DFO, at [jhinton@usccr.gov](mailto:jhinton@usccr.gov).

**SUPPLEMENTARY INFORMATION:**

*Public Call Information:* Dial: 800-667-5617, Conference ID: 7455125.

Members of the public can listen to the discussion. This meeting is available to the public through the toll-free call-in number dial: 800-667-5617, Conference ID: 7455125. 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](mailto:jhinton@usccr.gov). Records of the meeting will be available via [www.facadatabase.gov](http://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 Introductions
- Discussion: Voting Right Issues in Florida
- Public Comment
- Adjournment

*Exceptional Circumstance:* Pursuant to 41 CFR 102-3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstances of the federal government shutdown.

Dated: March 27, 2019.

**David Mussatt,**

*Supervisory Chief, Regional Programs Unit.*

[FR Doc. 2019-06320 Filed 4-1-19; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF COMMERCE****International Trade Administration**

[C–570–107]

**Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Initiation of Countervailing Duty Investigation**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable March 26, 2019.

**FOR FURTHER INFORMATION CONTACT:** Benito Ballesteros at (202) 482–7425 or Christian Llinas at (202) 482–4877, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:****The Petition**

On March 6, 2019, the U.S. Department of Commerce (Commerce) received a countervailing duty (CVD) Petition concerning imports of wooden cabinets and vanities and components thereof (wooden cabinets and vanities) from the People's Republic of China (China).<sup>1</sup> The Petition, was filed in proper form by the American Kitchen Cabinet Alliance (the petitioner).<sup>2</sup> The CVD Petition was accompanied by an antidumping duty (AD) Petition concerning imports of wooden cabinets and vanities from China.

Between March 11 and 20, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petition.<sup>3</sup> The petitioner filed

responses to these requests between March 12 and March 22, 2019.<sup>4</sup>

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Government of China is providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of wooden cabinets and vanities in China, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing wooden cabinets and vanities in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating a CVD investigation, the Petition is accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed this Petition on behalf of the domestic industry because the petitioner is an interested party as defined in section 771(9)(E) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested CVD investigation.<sup>5</sup>

**Period of Investigation**

Because the Petition was filed on March 6, 2019, the period of investigation (POI) is January 1, 2018, through December 31, 2018.

**Scope of the Investigation**

The merchandise covered by this investigation consists of wooden cabinets and vanities from China. For a full description of the scope of this

investigation, see the Appendix to this notice.

**Scope Comments**

During our review of the Petition, we contacted the petitioner regarding the proposed scope language to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic industry is seeking relief.<sup>6</sup> As a result, the scope of the Petition was modified to clarify the description of merchandise covered by the Petition. The description of the merchandise covered by this investigation, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope).<sup>7</sup> Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,<sup>8</sup> all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on April 15, 2019, which is the next business day after 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on April 25, 2019, which is 10 calendar days from the initial comments deadline.<sup>9</sup>

Commerce requests that any factual information parties consider relevant to the scope of the investigation be submitted during this period. However, if a party subsequently finds that

<sup>1</sup> See petitioner's letter, "Petitions for the Imposition of Antidumping and Countervailing Duties on Wooden Cabinets and Vanities from the People's Republic of China," dated March 6, 2019 (Petition); see also Memorandum, "Phone Call with Counsel to the Petitioner," dated March 26, 2019.

<sup>2</sup> The Alliance is comprised of ACProducts, Inc., American Woodmark Corporation, Bellmont Cabinet Co., Bertch Cabinet Manufacturing, The Corsi Group, Crystal Cabinet Works, Inc., Dura Supreme Cabinetry, Jim Bishop Cabinets, Inc., Kitchen Compact, Inc., Koch & Co., Inc., Kountry Wood Products, LLC, Lanz Cabinets Incorporated, Leedo Cabinetry, Marsh Furniture Company, Master WoodCraft Cabinetry LLC, MasterBrand Cabinets, Inc., Nation's Cabinetry, Showplace Wood Products, Inc., Smart Cabinetry, Tru Cabinetry, Wellborn Cabinet, Inc., Wellborn Forest Products, Inc., Woodland Cabinetry, Inc., Woodmont Cabinetry, W. W. Wood Products, Inc. The Alliance also has two additional members, the identities of which are proprietary.

<sup>3</sup> See Commerce Letters, "Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Supplemental Questions," dated March 11, 2019; "Petition for the Imposition of Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Supplemental Questions," dated

March 12, 2019; Commerce Memorandum, "Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Phone Call with Counsel to the Petitioner," dated March 18, 2019; and Commerce Memorandum, "Phone Call with U.S. Customs and Border Protection Officials and Counsel to the Petitioner," dated March 20, 2019 (March 20, 2019 Memorandum).

<sup>4</sup> See the petitioner's Letters, "Wooden Cabinets and Vanities from the People's Republic of China: Petitioner's Responses to Supplemental Questions Regarding Petition Volume I Injury," dated March 12, 2019 (General Issues Supplement); "Wooden Cabinets and Vanities from the People's Republic of China: Petitioner's Responses to Supplemental Questions Regarding Petition Volume III China CVD," dated March 14, 2019; and "Wooden Cabinets and Vanities from the People's Republic of China: Second Supplemental Responses—Volume I Injury," dated March 20, 2019.

<sup>5</sup> See "Countervailing Duty Investigation Initiation Checklist: Wooden Cabinets and Vanities from the People's Republic of China (China CVD Initiation Checklist). This checklist is dated concurrently with, and hereby adopted by, this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

<sup>6</sup> See Memorandum, "Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Phone Call with Counsel to the Petitioner," dated March 11, 2019; "Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Phone Call with U.S. Customs and Border Protection Officials and Counsel to the Petitioner," dated March 20, 2019; "Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Phone Call with Counsel to the Petitioner," dated March 22, 2019; see also "Wooden Cabinets and Vanities from the People's Republic of China: Petitioner's Response to Department of Commerce March 20, 2019 Memorandum," dated March 22, 2019.

<sup>7</sup> See *Antidumping Duties; Countervailing Duties, Final Rule*, 62 FR 27296, 27323 (May 19, 1997).

<sup>8</sup> See 19 CFR 351.102(b)(21) (defining "factual information").

<sup>9</sup> See 19 CFR 351.303(b).

additional factual information pertaining to the scope of the investigation may be relevant, the party may contact Commerce and request permission to submit the additional information. All such submissions must be filed on the records of the concurrent AD and CVD investigations.

### Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).<sup>10</sup> An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

### Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified China of the receipt of the Petition and provided it the opportunity for consultations with respect to the CVD Petition.<sup>11</sup> China did not request consultations.

### Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D)

of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

Section 771(4)(A) of the Act defines the "industry" as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,<sup>12</sup> they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.<sup>13</sup>

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the Petition.<sup>14</sup> Based on our analysis of the information submitted on the record, we have determined that wooden cabinets and vanities, as defined in the scope, constitute a single domestic like product, and we have analyzed industry

support in terms of that domestic like product.<sup>15</sup>

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the "Scope of the Investigation," in the Appendix to this notice. To establish industry support, the petitioner provided 2018 shipments of the domestic like product for the U.S. producers that support the Petition.<sup>16</sup> The petitioner estimated the production of the domestic like product for the entire domestic industry based on shipment value data, because production quantity data for the entire domestic industry are not available, and shipments are a close approximation of production in the wooden cabinets and vanities industry.<sup>17</sup> The petitioner compared the shipments of the companies supporting the Petition to the estimated total 2018 shipments of the domestic like product for the entire domestic industry.<sup>18</sup> We relied on data provided by the petitioner for purposes of measuring industry support.<sup>19</sup>

On March 20, 2019, we received comments on industry support from American Home Furnishings Alliance (AHFA), an alliance representing the U.S. residential furniture industry, and Fabuwood Cabinetry Corp. (Fabuwood), a U.S. importer.<sup>20</sup> On March 22, 2019, we received industry support comments

<sup>15</sup> For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, see Countervailing Duty Investigation Initiation Checklist: Wooden Cabinets and Vanities from the People's Republic of China (China CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petition Covering Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

<sup>16</sup> See Volume I of the Petition, at 2–4 and Exhibits I–3, I–5, and I–7; see also General Issues Supplement, at 10–14 and Exhibits I–Supp–5, I–Supp–8 and I–Supp–12.

<sup>17</sup> *Id.* at 3 and Exhibits I–3, I–4 and I–15; see also General Issues Supplement, at 9.

<sup>18</sup> See General Issues Supplement, at 10, 13, and 14.

<sup>19</sup> See Volume I of the Petition, at 2–4 and Exhibits I–3, I–4, I–5, and I–7; see also General Issues Supplement, at 9–14 and Exhibits I–Supp–5, I–Supp–8, I–Supp–10, I–Supp–11, and I–Supp–12. For further discussion, see China CVD Initiation Checklist, at Attachment II.

<sup>20</sup> See AHFA's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Comments on Industry Support," dated March 20, 2019 (AHFA's Letter). See Fabuwood's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Request to Dismiss Petition or Otherwise Postpone Initiation," dated March 20, 2019 (Fabuwood's Letter).

<sup>10</sup> See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011); see also *Enforcement and Compliance; Change of Electronic Filing System Name*, 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at <https://access.trade.gov/help.aspx> and a handbook can be found at <https://access.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf>.

<sup>11</sup> See Commerce Letter, "Countervailing Duty Petition on Wooden Cabinets and Vanities from the People's Republic of China: Invitation for Consultations to Discuss the Petition" dated March 11, 2019.

<sup>12</sup> See section 771(10) of the Act.

<sup>13</sup> See *USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd. v. United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

<sup>14</sup> See Volume I of the Petition, at 18–20; see also General Issues Supplement, at 6–7.

from Huisen Furniture Longnan Co. Ltd. (Huisen), a Chinese producer and exporter of living room floor-standing furniture, and Kimball Hospitality Inc. (Kimball), a U.S. producer and importer of hospitality furniture.<sup>21</sup> The petitioner responded to the industry support comments from AHFA, Fabuwood, Huisen, and Kimball on March 25, 2019.<sup>22</sup>

Our review of the data provided in the Petition, the General Issues Supplement, the Petitioner's Letter, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.<sup>23</sup> First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (e.g., polling).<sup>24</sup> Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.<sup>25</sup> Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.<sup>26</sup> Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

### Injury Test

Because China is a "Subsidies Agreement Country" within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from China

materially injure, or threaten material injury to, a U.S. industry.

### Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.<sup>27</sup>

The petitioner contends that the industry's injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; underselling and price depression or suppression; lost sales and revenues; closure of manufacturing facilities and hindered planned expansion efforts due to market conditions caused by subject imports; and a decline in the domestic industry's U.S. production, capacity utilization, commercial shipments, employment, and financial performance.<sup>28</sup> We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.<sup>29</sup>

### Initiation of CVD Investigation

Based on the examination of the Petition, we find that the Petition meets the requirements of section 702 of the Act. Therefore, we are initiating a CVD investigation to determine whether imports of wooden cabinets and vanities from China benefit from countervailable subsidies conferred by the Government of China. Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation, in whole or part, on 36 of the 37 alleged programs. For a full discussion of the basis for our decision to initiate on each program, see China CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on

ACCESS. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

### Respondent Selection

Commerce normally selects respondents in a CVD investigation using CBP entry data. However, for this investigation, the HTSUS numbers the subject merchandise would enter under include basket categories containing products unrelated to wooden cabinets and vanities, and the reported entry data contain differing units of quantity. Therefore, we cannot rely on CBP entry data in selecting respondents. Instead, for this investigation, Commerce will request quantity and value (Q&V) information from known exporters and producers identified, with complete contact information, in the Petition. In addition, Commerce will post the Q&V questionnaire along with filing instructions on the Enforcement and Compliance website at <http://www.trade.gov/enforcement/news.asp>.

The petitioner named 727 companies in China as producers/exporters of wooden cabinets and vanities.<sup>30</sup> After considering our resources, Commerce has determined that we do not have sufficient administrative resources to issue Q&V questionnaires to all 727 identified producers and exporters. Therefore, Commerce has determined to limit the number of Q&V questionnaires we will send out to exporters and producers identified in U.S. Customs and Border Protection (CBP) data for U.S. imports of wooden cabinets and vanities during the POI under the appropriate Harmonized Tariff Schedule of the United States number listed in the "Scope of the Investigation," in the Appendix. Accordingly, Commerce will send Q&V questionnaires to the largest producers and exporters that are identified in the CBP data for which there is address information on the record.

On March 26, 2019, Commerce released CBP data on imports of wooden cabinets and vanities from China under APO to all parties with access to information protected by APO and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of this investigation.<sup>31</sup> We

<sup>21</sup> See Huisen's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Comments on Industry Support," dated March 22, 2019 (Huisen's Letter).

<sup>22</sup> See Petitioner's Letter, "Wooden, Cabinets and Vanities from the People's Republic of China: Petitioners Response to Request to Various Parties' Requests to Dismiss or Postpone," dated March 25, 2019 (Petitioner's Letter).

<sup>23</sup> See China CVD Initiation Checklist, at Attachment II.

<sup>24</sup> *Id.*; see also section 702(c)(4)(D) of the Act.

<sup>25</sup> See China CVD Initiation Checklist, at Attachment II.

<sup>26</sup> *Id.*

<sup>27</sup> See General Issues Supplement, at 15–16 and Exhibits I–Supp–10 and I–Supp–13.

<sup>28</sup> See Volume I of the Petitions, at 15–18, 21–35 and Exhibits I–4, I–11 through I–29; see also General Issues Supplement, at 14–16 and Exhibits I–Supp–10 and I–Supp–13.

<sup>29</sup> See China CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China (Attachment III).

<sup>30</sup> See Petition Volume I at Exhibit I–9; see also General Issues Supplement at Exhibit I–Supp–1.

<sup>31</sup> See Memorandum, "Countervailing Duty Investigation of Wooden Cabinets and Vanities from

further stated that we will not accept rebuttal comments.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce website at <http://enforcement.trade.gov/apo>.

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. We intend to finalize our decisions regarding respondent selection within 20 days of publication of this notice.

Producers/exporters of wooden cabinets and vanities from China that do not receive Q&V questionnaires by mail may still submit a response to the Q&V questionnaire and can obtain a copy from the Enforcement & Compliance website. The Q&V response must be submitted by the relevant China exporters/producers no later than April 15, 2019. All Q&V responses must be filed electronically via ACCESS.

#### Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to China *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

#### ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

#### Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition were filed, whether there is a reasonable indication that imports of wooden cabinets and vanities from China are materially injuring, or threatening material injury to, a U.S. industry.<sup>32</sup> A negative ITC determination in any country will result in the investigation being terminated with respect to that country.<sup>33</sup> Otherwise, this investigation will proceed according to statutory and regulatory time limits.

#### Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence

submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted<sup>34</sup> and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.<sup>35</sup> Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

#### Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule*, 78 FR 57790 (September 20, 2013), available at <http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in this investigation.

#### Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.<sup>36</sup> Parties must use the certification formats provided in 19 CFR 351.303(g).<sup>37</sup> Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

#### Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures*, 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (e.g., the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act and 19 CFR 351.203(c).

Dated: March 26, 2019.

#### Gary Taverman,

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

#### Appendix

##### Scope of the Investigation

The merchandise subject to this investigation consists of wooden cabinets and vanities that are for permanent installation (including floor mounted, wall mounted, ceiling hung or by attachment of plumbing), and wooden components thereof. Wooden cabinets and vanities and wooden components are made substantially of wood products, including solid wood and engineered wood products (including those made from wood particles, fibers, or other wooden materials such as plywood, strand board, block board, particle board, or fiberboard), or bamboo. Wooden cabinets and vanities consist of a cabinet box (which typically includes a top, bottom, sides, back, base blockers, ends/end panels, stretcher rails, toe kicks, and/or shelves) and may or may not include a frame, door, drawers and/or shelves. Subject merchandise includes wooden cabinets and vanities with or without wood veneers, wood, paper or other overlays, or laminates, with or without non-

<sup>36</sup> See section 782(b) of the Act.

<sup>37</sup> See *Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (*Final Rule*); see also frequently asked questions regarding the *Final Rule*, available at [http://enforcement.trade.gov/tlei/notices/factual\\_info\\_final\\_rule\\_FAQ\\_07172013.pdf](http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf).

China: Release of U.S. Customs and Border Protection Data;" dated March 26, 2019.

<sup>32</sup> See section 703(a)(2) of the Act.

<sup>33</sup> See section 703(a)(1) of the Act.

<sup>34</sup> See 19 CFR 351.301(b).

<sup>35</sup> See 19 CFR 351.301(b)(2).

wood components or trim such as metal, marble, glass, plastic, or other resins, whether or not surface finished or unfinished, and whether or not completed.

Wooden cabinets and vanities are covered by the investigation whether or not they are imported attached to, or in conjunction with, faucets, metal plumbing, sinks and/or sink bowls, or countertops. If wooden cabinets or vanities are imported attached to, or in conjunction with, such merchandise, only the wooden cabinet or vanity is covered by the scope.

Subject merchandise includes the following wooden component parts of cabinets and vanities: (1) Wooden cabinet and vanity frames (2) wooden cabinet and vanity boxes (which typically include a top, bottom, sides, back, base blockers, ends/end panels, stretcher rails, toe kicks, and/or shelves), (3) wooden cabinet or vanity doors, (4) wooden cabinet or vanity drawers and drawer components (which typically include sides, backs, bottoms, and faces), (5) back panels and end panels, (6) and desks, shelves, and tables that are attached to or incorporated in the subject merchandise.

Subject merchandise includes all unassembled, assembled and/or “ready to assemble” (RTA) wooden cabinets and vanities, also commonly known as “flat packs,” except to the extent such merchandise is already covered by the scope of antidumping and countervailing duty orders on *Hardwood Plywood from the People’s Republic of China*. See *Certain Hardwood Plywood Products from the People’s Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order*, 83 FR 504 (January 4, 2018); *Certain Hardwood Plywood Products from the People’s Republic of China: Countervailing Duty Order*, 83 FR 513 (January 4, 2018). RTA wooden cabinets and vanities are defined as cabinets or vanities packaged so that at the time of importation they may include: (1) Wooden components required to assemble a cabinet or vanity (including drawer faces and doors); and (2) parts (e.g., screws, washers, dowels, nails, handles, knobs, adhesive glues) required to assemble a cabinet or vanity. RTAs may enter the United States in one or in multiple packages.

Subject merchandise also includes wooden cabinets and vanities and in-scope components that have been further processed in a third country, including but not limited to one or more of the following: Trimming, cutting, notching, punching, drilling, painting, staining, finishing, assembly, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this investigation, if entered separate from a wooden cabinet or vanity are:

(1) Aftermarket accessory items which may be added to or installed into an interior of a cabinet and which are not considered a structural or core component of a wooden cabinet or vanity. Aftermarket accessory items may be made of wood, metal, plastic, composite material, or a combination thereof that can be inserted into a cabinet and which

are utilized in the function of organization/ accessibility on the interior of a cabinet; and include:

- Inserts or dividers which are placed into drawer boxes with the purpose of organizing or dividing the internal portion of the drawer into multiple areas for the purpose of containing smaller items such as cutlery, utensils, bathroom essentials, etc.

- Round or oblong inserts that rotate internally in a cabinet for the purpose of accessibility to foodstuffs, dishware, general supplies, etc.

(2) Solid wooden accessories including corbels and rosettes, which serve the primary purpose of decoration and personalization.

(3) Non-wooden cabinet hardware components including metal hinges, brackets, catches, locks, drawer slides, fasteners (nails, screws, tacks, staples), handles, and knobs.

Also excluded from the scope of this investigation are:

(1) All products covered by the scope of the antidumping duty order on *Wooden Bedroom Furniture from the People’s Republic of China*. See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People’s Republic of China*, 70 FR 329 (January 4, 2005).

(2) All products covered by the scope of the antidumping and countervailing duty orders on *Hardwood Plywood from the People’s Republic of China*. See *Certain Hardwood Plywood Products from the People’s Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order*, 83 FR 504 (January 4, 2018); *Certain Hardwood Plywood Products from the People’s Republic of China: Countervailing Duty Order*, 83 FR 513 (January 4, 2018).

Imports of subject merchandise are classified under Harmonized Tariff Schedule of the United States (HTSUS) statistical numbers 9403.40.9060 and 9403.60.8081. The subject component parts of wooden cabinets and vanities may be entered into the United States under HTSUS statistical number 9403.90.7080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2019–06387 Filed 4–1–19; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A–570–848]

#### **Freshwater Crawfish Tail Meat From the People’s Republic of China: Preliminary Results of Antidumping Duty New Shipper Review; 2017–2018**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (Commerce) preliminarily determines

that Nanjing Yinxiangchen International Trade Co., Ltd. (Nanjing Yinxiangchen) did not make sales of subject merchandise at prices below normal value during the period of review (POR), September 1, 2017, through February 28, 2018. We invite interested parties to comment on the preliminary results.

**DATES:** Applicable April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Hermes Pinilla (202) 482–3477, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Commerce is conducting a new shipper review of the antidumping duty order on freshwater crawfish tail meat from the People’s Republic of China (China). The new shipper review covers Nanjing Yinxiangchen. Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.<sup>1</sup> If the new deadline falls on a non-business day, in accordance with Commerce’s practice, the deadline will become the next business day. Accordingly, the revised deadline for the final results of this review is now March 26, 2019.

##### **Scope of the Order**

The merchandise subject to the antidumping duty order is freshwater crawfish tail meat, which is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 1605.40.10.10, 1605.40.10.90, 0306.19.00.10, and 0306.29.00.00. On February 10, 2012, Commerce added HTSUS classification number 0306.29.01.00 to the scope description pursuant to a request by U.S. Customs and Border Protection (CBP). On September 21, 2018, Commerce added HTSUS classification numbers 0306.39.0000 and 0306.99.0000 to the scope description pursuant to a request by CBP. While the HTSUS numbers are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.<sup>2</sup>

<sup>1</sup> See Memorandum, “Deadlines Affected by the Partial Shutdown of the Federal Government,” dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

<sup>2</sup> See Memorandum, “Freshwater Crawfish Tail Meat from the People’s Republic of China: Decision

Continued

**Separate Rate**

Commerce preliminarily determines that Nanjing Yinxiangchen is eligible to receive a separate rate in this review.<sup>3</sup>

**Methodology**

Commerce is conducting this review in accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214. Commerce calculated export price in accordance with section 772(c) of the Act. Because China is a non-market economy within the meaning of section 771(18) of the Act, Commerce calculated

normal value in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>, and to all parties in Commerce's Central Records Unit, Room B8024 of the main

Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at <http://enforcement.trade.gov/frn/>. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

**Preliminary Results of New Shipper Review**

As a result of the new shipper review, Commerce preliminarily determines that the following dumping margin exists:<sup>4</sup>

Exporter	Producer	Weighted-average margin (percent)
Nanjing Yinxiangchen International Trade Co. Ltd .....	Nanjing Yinxiangchen International Trade Co. Ltd .....	0.00

**Disclosure**

We intend to disclose calculations performed in these preliminary results to parties within five days after public announcement of the preliminary results.<sup>5</sup>

**Public Comment**

Pursuant to 19 CFR 351.309(c)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice.<sup>6</sup> Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.<sup>7</sup> Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.<sup>8</sup>

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.<sup>9</sup> Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3)

a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Unless the deadline is extended, Commerce intends to issue the final results of this new shipper review, including the results of its analysis of issues raised by parties in their comments, within 90 days after the publication of these preliminary results, pursuant to section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(i)(1).

**Assessment Rates**

Upon issuing the final results of this new shipper review, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.<sup>10</sup> If the respondent's weighted-average dumping margin is above *de minimis* (i.e., 0.50 percent) in the final results of this review, we will calculate an importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and, where possible, the total entered value of sales in accordance with 19 CFR 351.212(b)(1). Specifically, Commerce will apply the assessment rate calculation method adopted in *Final Modification for Reviews*.<sup>11</sup> Where an importer- (or customer-) specific *ad*

*valorem* rate is zero or *de minimis*, we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.<sup>12</sup>

For entries that were not reported in the U.S. sales database submitted by Nanjing Yinxiangchen examined during this review, Commerce will instruct CBP to liquidate such entries at the China-wide rate.

**Cash Deposit Requirements**

With regard to Nanjing Yinxiangchen, the respondent in this new shipper review, Commerce established a combination cash deposit rate consistent with its practice, as follows: (1) For subject merchandise produced and exported by Nanjing Yinxiangchen, the cash deposit rate will be the rate established in the final results of this new shipper review; (2) for subject merchandise exported by Nanjing Yinxiangchen but not produced by Nanjing Yinxiangchen the cash deposit rate will be the rate for the China-wide entity; and (3) for subject merchandise produced by Nanjing Yinxiangchen but not exported by Nanjing Yinxiangchen the cash deposit rate will be the rate applicable to the exporter. These deposit requirements shall remain in effect until further notice.

Memorandum for the Preliminary Results of the New Shipper Review: 2017–2018," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

<sup>3</sup> See Preliminary Decision Memorandum at 6–8, for more details.

<sup>4</sup> Commerce reached this conclusion based on the totality of the circumstances surrounding the reported sale for Nanjing Yinxiangchen. See

Preliminary Decision Memorandum at 2–3 *Bona Fides* Analysis section.

<sup>5</sup> See 19 CFR 351.224(b).

<sup>6</sup> See 19 CFR 351.309(c).

<sup>7</sup> See 19 CFR 351.309(d).

<sup>8</sup> See 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

<sup>9</sup> See 19 CFR 351.310(c).

<sup>10</sup> See 19 CFR 351.212(b)(1).

<sup>11</sup> See *Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification*, 77 FR 8101, 8103 (February 14, 2012) (*Final Modification for Reviews*).

<sup>12</sup> See 19 CFR 351.106(c)(2).

## Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during these PORs. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

## Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of 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 sanctionable violation.

Commerce is issuing and publishing the preliminary results of this new shipper review in accordance with sections 751(a)(2)(B) and 777(i) of the Act, and 19 CFR 351.214 and 351.221(b)(4).

Dated: March 27, 2019.

### Gary Taverman,

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix

### List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. *Bona Fides* Analysis
- V. Discussion of the Methodology
  - A. Non-Market-Economy Country Status
  - B. Surrogate Country
  - C. Separate Rate
    1. Absence of *De Jure* Control
    2. Absence of *De Facto* Control
  - D. Fair Value Comparisons
    1. Determination of Comparison Method
    2. Results of the Differential Pricing Analysis
  - E. U.S. Price
  - F. Date of Sale
  - G. Normal Value
  - H. Surrogate Values
- VI. Currency Conversion
- VII. Recommendation

[FR Doc. 2019-06314 Filed 4-1-19; 8:45 am]

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## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-570-106]

### Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable March 26, 2019.

**FOR FURTHER INFORMATION CONTACT:** Amanda Brings at (202) 482-3927 or Rachel Greenberg at (202) 482-0652, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

### SUPPLEMENTARY INFORMATION:

#### The Petition

On March 6, 2019, the U.S. Department of Commerce (Commerce) received an antidumping duty (AD) Petition concerning imports of wooden cabinets and vanities and components thereof (wooden cabinets and vanities) from the People's Republic of China (China), filed in proper form on behalf of the American Kitchen Cabinet Alliance (the petitioner).<sup>1</sup> The AD Petition was accompanied by a countervailing duty (CVD) Petition concerning imports of wooden cabinets and vanities from China.

Between March 11 and 20, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petition.<sup>2</sup> The petitioner filed responses to these requests between March 12 and 22, 2019.<sup>3</sup>

<sup>1</sup> See Petitioner's Letter, "Petitions for the Imposition of Antidumping and Countervailing Duties on Wooden Cabinets and Vanities from the People's Republic of China," dated March 6, 2019 (the Petition); see also Memorandum, "Phone Call with Counsel to the Petitioner," dated March 26, 2019.

<sup>2</sup> See Commerce's Letters, "Re: Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Supplemental Questions," dated March 11, 2019 (General Issues Supplemental Questionnaire) and "Re: Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Wooden Cabinets and Vanities from the People's Republic of China: Supplemental Questions," dated March 11, 2019 (AD Supplemental Questionnaire). See also Memorandum, "Phone Call with Counsel to the Petitioner," dated March 18, 2019 (March 18, 2019 Memorandum) and Memorandum, "Phone Call with U.S. Customs and Border Protection Officials and Counsel to the Petitioner," dated March 20, 2019 (March 20, 2019 Memorandum).

<sup>3</sup> See Petitioner's Letter, "Wooden Cabinets and Vanities from the People's Republic of China:

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of wooden cabinets and vanities from China are being, or are likely to be, sold in the United States at less-than-fair value (LTFV) within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing wooden cabinets and vanities in the United States. Consistent with section 732(b)(1) of the Act, the Petition is accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed this Petition on behalf of the domestic industry because the petitioner is an interested party as defined in section 771(9)(E) of the Act. Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested AD investigation.<sup>4</sup>

#### Period of Investigation

Because the Petition was filed on March 6, 2019, the period of investigation (POI) is July 1, 2018, through December 31, 2018.

#### Scope of the Investigation

The merchandise covered by this investigation consists of wooden cabinets and vanities from China. For a full description of the scope of this investigation, see the Appendix to this notice.

#### Comments on Scope of the Investigation

During our review of the Petition, we contacted the petitioner regarding the proposed scope to ensure that the scope language in the Petition is an accurate

Petitioner's Responses to Supplemental Questions Regarding Petition Volume I Injury," dated March 12, 2019 (General Issues Supplement); Petitioner's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Petitioner's Responses to Supplemental Questions Regarding Petition Volume II China AD," dated March 12, 2019 (AD Supplement); Petitioner's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Second Supplemental Responses—Volume I Injury," dated March 20, 2019 (Second General Issues Supplement); Petitioner's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Second Supplemental Responses—Volume II Injury," dated March 20, 2019 (Second AD Supplement); and Petitioner's Letter, "Wooden Cabinets and Vanities from the People's Republic of China: Petitioner's Response to Department of Commerce's March 20, 2019 Memorandum," dated March 22, 2019 (Scope Clarification).

<sup>4</sup> See "Antidumping Duty Investigation Initiation Checklist: Wooden Cabinets and Vanities from the People's Republic of China." (AD Initiation Checklist). This checklist is dated concurrently with, and hereby adopted by, this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

reflection of the products for which the domestic industry is seeking relief.<sup>5</sup> As a result, the scope of the Petition was modified to clarify the description of the merchandise covered by the Petition. The description of the merchandise covered by this investigation, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope).<sup>6</sup> Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,<sup>7</sup> all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on April 15, 2019, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on April 25, 2019, which is 10 calendar days from the initial comment deadline.<sup>8</sup>

Commerce requests that any factual information the parties consider relevant to the scope of the investigation be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact Commerce and request permission to submit the additional information. All such comments must also be filed on the record of the concurrent CVD investigation.

### Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).<sup>9</sup>

<sup>5</sup> See General Issues Supplement; see also March 18, 2019 Memorandum, March 20, 2019 Memorandum, and Scope Clarification; see also Memorandum, "Phone Call with Counsel to the Petitioner," dated March 21, 2019.

<sup>6</sup> See *Antidumping Duties; Countervailing Duties*, 62 FR 27296, 27323 (May 19, 1997).

<sup>7</sup> See 19 CFR 351.102(b)(21) (defining "factual information").

<sup>8</sup> See 19 CFR 351.303(b).

<sup>9</sup> See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011); see also *Enforcement and Compliance; Change of Electronic Filing System Name*, 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using

An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

### Comments on Product Characteristics for AD Questionnaires

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of wooden cabinets and vanities to be reported in response to Commerce's AD questionnaire. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors of production (FOPs) accurately, as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. In order to consider the suggestions of interested parties in developing and issuing the AD questionnaire, all comments must be filed by 5:00 p.m. ET on April 15, 2019, which is 20 calendar days from the signature date of this notice.<sup>10</sup> Any rebuttal comments must be filed by 5:00 p.m. ET on April 25, 2019. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of this AD investigation.

### Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic

ACCESS can be found at <https://access.trade.gov/help.aspx> and a handbook can be found at <https://access.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf>.

<sup>10</sup> See 19 CFR 351.303(b).

producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the "industry."

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,<sup>11</sup> they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.<sup>12</sup>

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation" (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the Petition.<sup>13</sup> Based on our analysis of the information submitted on the record, we have determined that wooden cabinets and vanities, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.<sup>14</sup>

<sup>11</sup> See section 771(10) of the Act.

<sup>12</sup> See *USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd. v. United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

<sup>13</sup> See Volume I of the Petition, at 18–20; see also General Issues Supplement, at 6–7.

<sup>14</sup> For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, see AD Initiation

In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the “Scope of the Investigation,” in the Appendix to this notice. To establish industry support, the petitioner provided 2018 shipments of the domestic like product for the U.S. producers that support the Petition.<sup>15</sup> The petitioner estimated the production of the domestic like product for the entire domestic industry based on shipment value data, because production quantity data for the entire domestic industry are not available, and shipments are a close approximation of production in the wooden cabinets and vanities industry.<sup>16</sup> The petitioner compared the shipments of the companies supporting the Petition to the estimated total 2018 shipments of the domestic like product for the entire domestic industry.<sup>17</sup> We relied on data provided by the petitioner for purposes of measuring industry support.<sup>18</sup>

On March 20, 2019, we received comments on industry support from American Home Furnishings Alliance (AHFA), an alliance representing the U.S. residential furniture industry, and Fabuwood Cabinetry Corp. (Fabuwood), a U.S. importer.<sup>19</sup> On March 22, 2019, we received industry support comments from Huisen Furniture Longnan Co. Ltd. (Huisen), a Chinese producer and exporter of living room floor-standing furniture, and Kimball Hospitality Inc. (Kimball), a U.S. producer and importer of hospitality furniture.<sup>20</sup> The petitioner

responded to the industry support comments from AHFA, Fabuwood, Huisen, and Kimball on March 25, 2019.<sup>21</sup>

Our review of the data provided in the Petition, the General Issues Supplement, the Petitioner’s Letter, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.<sup>22</sup> First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (e.g., polling).<sup>23</sup> Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.<sup>24</sup> Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.<sup>25</sup> Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

#### **Allegations and Evidence of Material Injury and Causation**

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.<sup>26</sup>

The petitioner contends that the industry’s injured condition is illustrated by a significant and increasing volume of subject imports; reduced market share; underselling and

price depression or suppression; lost sales and revenues; closure of manufacturing facilities and hindered planned expansion efforts due to market conditions caused by subject imports; a decline in the domestic industry’s U.S. production, capacity utilization, commercial shipments, employment, and financial performance; and the magnitude of the alleged dumping margins.<sup>27</sup> We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.<sup>28</sup>

#### **Allegations of Sales at Less Than Fair Value**

The following is a description of the allegation of sales at LTFV upon which Commerce based its decision to initiate an AD investigation of imports of wooden cabinets and vanities from China. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the AD Initiation Checklist.

#### **Export Price**

The petitioner based export price (EP) on an offer for sale for wooden cabinets produced in China and offered for sale to a customer in the United States.<sup>29</sup> The petitioner made deductions from U.S. price for foreign inland freight and foreign brokerage and handling charges.<sup>30</sup>

#### **Normal Value**

With respect to China, Commerce considers China to be an NME country.<sup>31</sup> In accordance with section

Checklist, at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Wooden Cabinets and Vanities from the People’s Republic of China (Attachment II).

<sup>15</sup> See Volume I of the Petition, at 2–4 and Exhibits I–3, I–5, and I–7; see also General Issues Supplement, at 10–14 and Exhibits I–Supp–5, I–Supp–8 and I–Supp–12.

<sup>16</sup> See Volume I of the Petition at 3 and Exhibits I–3, I–4 and I–15; see also General Issues Supplement, at 9.

<sup>17</sup> See General Issues Supplement, at 10, 13, and 14.

<sup>18</sup> See Volume I of the Petition, at 2–4 and Exhibits I–3, I–4, I–5, and I–7; see also General Issues Supplement, at 9–14 and Exhibits I–Supp–5, I–Supp–8, I–Supp–10, I–Supp–11, and I–Supp–12. For further discussion, see AD Initiation Checklist, at Attachment II.

<sup>19</sup> See AHFA’s Letter, “Wooden Cabinets and Vanities from the People’s Republic of China: Comments on Industry Support,” dated March 20, 2019 (AHFA’s Letter). See Fabuwood’s Letter, “Wooden Cabinets and Vanities from the People’s Republic of China: Request to Dismiss Petitions or Otherwise Postpone Initiation,” dated March 20, 2019 (Fabuwood’s Letter).

<sup>20</sup> See Huisen’s Letter, “Wooden Cabinets and Vanities from the People’s Republic of China: Comments on Industry Support,” dated March 22, 2019 (Huisen’s Letter).

<sup>21</sup> See Petitioner’s Letter, “Wooden, Cabinets and Vanities from the People’s Republic of China: Petitioners Response to Request to Various Parties’ Requests to Dismiss or Postpone,” dated March 25, 2019 (Petitioner’s Letter).

<sup>22</sup> See AD Initiation Checklist, at Attachment II.

<sup>23</sup> See section 732(c)(4)(D) of the Act; see also AD Initiation Checklist, at Attachment II.

<sup>24</sup> See AD Initiation Checklist, at Attachment II.

<sup>25</sup> *Id.*

<sup>26</sup> See General Issues Supplement, at 15–16 and Exhibits I–Supp–10 and I–Supp–13.

<sup>27</sup> See Volume I of the Petitions, at 15–18, 21–35 and Exhibits I–4, I–11 through I–29; see also General Issues Supplement, at 14–16 and Exhibits I–Supp–10 and I–Supp–13.

<sup>28</sup> See AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Wooden Cabinets and Vanities from the People’s Republic of China (Attachment III).

<sup>29</sup> See Volume II of the Petition, at 3 and Exhibit II–2; see also AD Supplement, at 1 and Exhibit II–Supp–2.

<sup>30</sup> See Volume II of the Petition, at 5–7 and Exhibit II–3, Exhibit II–7, Exhibit II–12; see also AD Supplement, at 3 and Exhibit II–Supp–3, Exhibit II–Supp–4, Exhibit II–Supp–5.

<sup>31</sup> See *Antidumping Duty Investigation of Certain Aluminum Foil from the People’s Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination*, 82 FR 50858, 50861 (November 2, 2017), and accompanying decision memorandum, *China’s Status as a Non-Market*

771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by Commerce. Therefore, we continue to treat China as an NME country for purposes of the initiation of this investigation. Accordingly, NV in China is appropriately based on FOPs valued in a surrogate market economy country, in accordance with section 773(c) of the Act.<sup>32</sup>

The Petition claims that Brazil is an appropriate surrogate country for China because it is a market economy that is at a level of economic development comparable to that of China and it is a significant producer of comparable merchandise.<sup>33</sup> The petitioner provided publicly available information from Brazil to value all FOPs. Based on the information provided by the petitioner, we determine that it is appropriate to use Brazil as a surrogate country for initiation purposes.

Interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs within 30 days before the scheduled date of the preliminary determination.

#### Factors of Production

Because information regarding the volume of inputs consumed by the Chinese producer/exporter was not reasonably available, the Petition used the product-specific consumption rates of a U.S. wooden cabinets and vanities producer as a surrogate to estimate the Chinese manufacturer's FOPs.<sup>34</sup> The Petition valued the estimated FOPs using surrogate values from Brazil, as noted above.<sup>35</sup> The Petition used an average exchange rate to convert the data to U.S. dollars, where applicable. The petitioner calculated factory overhead, selling, general and administrative expenses, and profit based on the experience of a Brazilian producer of wooden cabinets.<sup>36</sup>

#### Fair Value Comparisons

Based on the data provided by the Petition, there is reason to believe that imports of wooden cabinets and vanities from China are being, or are likely to be,

*Economy, unchanged in Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value*, 83 FR 9282 (March 5, 2018).

<sup>32</sup> See AD Initiation Checklist.

<sup>33</sup> *Id.* at 9–10 and Exhibit II–9, Exhibit II–10.

<sup>34</sup> *Id.* at 2, 10–11 and Exhibit II–11, Exhibit II–12.

<sup>35</sup> *Id.* at 14–17.

<sup>36</sup> See Volume II of the Petition at 15–17 and Exhibit II–21 and Exhibit II–22.

sold in the United States at LTFV. Based on comparisons of EP to NV, in accordance with sections 772 and 773 of the Act, the estimated dumping margins for wooden cabinets and vanities from China range from 177.36 to 262.18 percent.<sup>37</sup>

#### Initiation of LTFV Investigation

Based upon the examination of the Petition on wooden cabinets and vanities from China, we find that the Petition meets the requirements of section 732 of the Act. Therefore, we are initiating an AD investigation to determine whether imports of wooden cabinets and vanities from China are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

#### Respondent Selection

The petitioner named 727 companies in China as producers/exporters of wooden cabinets and vanities.<sup>38</sup> After considering our resources, Commerce has determined that we do not have sufficient administrative resources to issue quantity and value (Q&V) questionnaires to all 727 identified producers and exporters. Therefore, Commerce has determined to limit the number of Q&V questionnaires we will send out to exporters and producers identified in U.S. Customs and Border Protection (CBP) data for U.S. imports of wooden cabinets and vanities during the POI under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the “Scope of the Investigation,” in the Appendix. Accordingly, Commerce will send Q&V questionnaires to the largest producers and exporters that are identified in the CBP data for which there is address information on the record.

On March 26, 2019, Commerce released CBP data on imports of wooden cabinets and vanities from China under APO to all parties with access to information protected by APO and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of this investigation.<sup>39</sup> We

<sup>37</sup> See Second AD Supplement at Exhibit II–Supp–2–3; see also AD Initiation Checklist.

<sup>38</sup> See Petition Volume I at Exhibit I–9; see also General Issues Supplement at Exhibit I–Supp–1.

<sup>39</sup> See Memorandum, “Less-Than-Fair-Value Investigation of Wooden Cabinets and Vanities from China: Release of U.S. Customs and Border Protection Data,” dated March 26, 2019.

further stated that we will not accept rebuttal comments.

In addition, Commerce will post the Q&V questionnaire along with filing instructions on the Enforcement and Compliance website at <http://www.trade.gov/enforcement/news.asp>. In accordance with our standard practice for respondent selection in AD cases involving NME countries, we intend to base respondent selection on the responses to the Q&V questionnaire that we receive.

Producers/exporters of wooden cabinets and vanities from China that do not receive Q&V questionnaires by mail may still submit a response to the Q&V questionnaire and can obtain a copy from the Enforcement & Compliance website. The Q&V response must be submitted by the relevant China exporters/producers no later than April 15, 2019. All Q&V responses must be filed electronically via ACCESS.

#### Separate Rates

In order to obtain separate-rate status in an NME investigation, exporters and producers must submit a separate-rate application.<sup>40</sup> The specific requirements for submitting a separate-rate application in the China investigation are outlined in detail in the application itself, which is available on Commerce's website at <http://enforcement.trade.gov/nme/nme-sep-rate.html>. The separate-rate application will be due 30 days after publication of this initiation notice.<sup>41</sup> Exporters and producers who submit a separate-rate application and have been selected as mandatory respondents will be eligible for consideration for separate-rate status only if they respond to all parts of Commerce's AD questionnaire as mandatory respondents. Commerce requires that companies from China submit a response to both the Q&V questionnaire and the separate-rate application by the respective deadlines in order to receive consideration for separate-rate status. Companies not filing a timely Q&V response will not receive separate rate consideration.

#### Use of Combination Rates

Commerce will calculate combination rates for certain respondents that are eligible for a separate rate in an NME

<sup>40</sup> See Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation Involving Non-Market Economy Countries (April 5, 2005), available at <http://enforcement.trade.gov/policy/bull05-1.pdf> (Policy Bulletin 05.1).

<sup>41</sup> Although in past investigations this deadline was 60 days, consistent with 19 CFR 351.301(a), which states that “the Secretary may request any person to submit factual information at any time during a proceeding,” this deadline is now 30 days.

investigation. The Separate Rates and Combination Rates Bulletin states:

{w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME Investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of "combination rates" because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the period of investigation.<sup>42</sup>

### Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the government of China via ACCESS. Because of the particularly large number of producers/exporters identified in the Petition, Commerce considers the service of the public version of the Petition to the foreign producers/exporters satisfied by delivery of the public version to the government of China, consistent with 19 CFR 351.203(c)(2).

### ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

### Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of wooden cabinets and vanities from China are materially injuring or threatening material injury to a U.S. industry.<sup>43</sup> A negative ITC determination will result in the investigation being terminated.<sup>44</sup> Otherwise, this investigation will proceed according to statutory and regulatory time limits.

### Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of

allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Any party, when submitting factual information, must specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted<sup>45</sup> and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.<sup>46</sup> Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Please review the regulations prior to submitting factual information in this investigation.

### Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule*, 78 FR 57790 (September 20, 2013), available at <http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in these investigations.

### Certification Requirements

Any party submitting factual information in an AD or CVD

proceeding must certify to the accuracy and completeness of that information.<sup>47</sup> Parties must use the certification formats provided in 19 CFR 351.303(g).<sup>48</sup> Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

### Notification to Interested Parties

Interested parties must submit applications for disclosure under administrative protective order (APO) in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures*, 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (e.g., the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: March 28, 2019.

### Gary Taverman,

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

### Appendix

#### Scope of the Investigation

The merchandise subject to this investigation consists of wooden cabinets and vanities that are for permanent installation (including floor mounted, wall mounted, ceiling hung or by attachment of plumbing), and wooden components thereof. Wooden cabinets and vanities and wooden components are made substantially of wood products, including solid wood and engineered wood products (including those made from wood particles, fibers, or other wooden materials such as plywood, strand board, block board, particle board, or fiberboard), or bamboo. Wooden cabinets and vanities consist of a cabinet box (which typically includes a top, bottom, sides, back, base blockers, ends/end panels, stretcher rails, toe kicks, and/or shelves) and may or may not include a frame, door, drawers and/or shelves. Subject merchandise includes wooden cabinets and vanities with or without wood veneers, wood, paper or other overlays, or laminates, with or without non-wood components or trim such as metal, marble, glass, plastic, or other resins,

<sup>47</sup> See section 782(b) of the Act.

<sup>48</sup> See also *Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (*Final Rule*). Answers to frequently asked questions regarding the *Final Rule* are available at [http://enforcement.trade.gov/tlei/notices/factual\\_info\\_final\\_rule\\_FAQ\\_07172013.pdf](http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf).

<sup>42</sup> See Policy Bulletin 05.1 at 6 (emphasis added).

<sup>43</sup> See section 733(a) of the Act.

<sup>44</sup> *Id.*

<sup>45</sup> See 19 CFR 351.301(b).

<sup>46</sup> See 19 CFR 351.301(b)(2).

whether or not surface finished or unfinished, and whether or not completed.

Wooden cabinets and vanities are covered by the investigation whether or not they are imported attached to, or in conjunction with, faucets, metal plumbing, sinks and/or sink bowls, or countertops. If wooden cabinets or vanities are imported attached to, or in conjunction with, such merchandise, only the wooden cabinet or vanity is covered by the scope.

Subject merchandise includes the following wooden component parts of cabinets and vanities: (1) Wooden cabinet and vanity frames (2) wooden cabinet and vanity boxes (which typically include a top, bottom, sides, back, base blockers, ends/end panels, stretcher rails, toe kicks, and/or shelves), (3) wooden cabinet or vanity doors, (4) wooden cabinet or vanity drawers and drawer components (which typically include sides, backs, bottoms, and faces), (5) back panels and end panels, (6) and desks, shelves, and tables that are attached to or incorporated in the subject merchandise.

Subject merchandise includes all unassembled, assembled and/or "ready to assemble" (RTA) wooden cabinets and vanities, also commonly known as "flat packs," except to the extent such merchandise is already covered by the scope of antidumping and countervailing duty orders on *Hardwood Plywood from the People's Republic of China*. See *Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order*, 83 FR 504 (January 4, 2018); *Certain Hardwood Plywood Products from the People's Republic of China: Countervailing Duty Order*, 83 FR 513 (January 4, 2018). RTA wooden cabinets and vanities are defined as cabinets or vanities packaged so that at the time of importation they may include: (1) Wooden components required to assemble a cabinet or vanity (including drawer faces and doors); and (2) parts (e.g., screws, washers, dowels, nails, handles, knobs, adhesive glues) required to assemble a cabinet or vanity. RTAs may enter the United States in one or in multiple packages.

Subject merchandise also includes wooden cabinets and vanities and in-scope components that have been further processed in a third country, including but not limited to one or more of the following: trimming, cutting, notching, punching, drilling, painting, staining, finishing, assembly, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this investigation, if entered separate from a wooden cabinet or vanity are:

(1) Aftermarket accessory items which may be added to or installed into an interior of a cabinet and which are not considered a structural or core component of a wooden cabinet or vanity. Aftermarket accessory items may be made of wood, metal, plastic, composite material, or a combination thereof that can be inserted into a cabinet and which are utilized in the function of organization/ accessibility on the interior of a cabinet; and include:

- Inserts or dividers which are placed into drawer boxes with the purpose of organizing or dividing the internal portion of the drawer into multiple areas for the purpose of containing smaller items such as cutlery, utensils, bathroom essentials, etc.

- Round or oblong inserts that rotate internally in a cabinet for the purpose of accessibility to foodstuffs, dishware, general supplies, etc.

(2) Solid wooden accessories including corbels and rosettes, which serve the primary purpose of decoration and personalization.

(3) Non-wooden cabinet hardware components including metal hinges, brackets, catches, locks, drawer slides, fasteners (nails, screws, tacks, staples), handles, and knobs.

Also excluded from the scope of this investigation are:

(1) All products covered by the scope of the antidumping duty order on *Wooden Bedroom Furniture from the People's Republic of China*. See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture From the People's Republic of China*, 70 FR 329 (January 4, 2005).

(2) All products covered by the scope of the antidumping and countervailing duty orders on *Hardwood Plywood from the People's Republic of China*. See *Certain Hardwood Plywood Products from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order*, 83 FR 504 (January 4, 2018); *Certain Hardwood Plywood Products from the People's Republic of China: Countervailing Duty Order*, 83 FR 513 (January 4, 2018).

Imports of subject merchandise are classified under Harmonized Tariff Schedule of the United States (HTSUS) statistical numbers 9403.40.9060 and 9403.60.8081. The subject component parts of wooden cabinets and vanities may be entered into the United States under HTSUS statistical number 9403.90.7080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2019-06388 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

RIN 0648-XG920

#### North Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The North Pacific Fishery Management Council (Council) Salmon

Bycatch Workshop will meet April 15, 2019 through April 16, 2019.

**DATES:** The meeting will be held on Monday, April 15, 2019, from 8:30 a.m. to 5 p.m. and Tuesday, April 16, 2019, from 8 a.m. to 12 p.m., Pacific Standard Time.

**ADDRESSES:** The meeting will be held in the Traynor Room, Building 4 at the Alaska Fisheries Science Center, 7600 Sand Point Way NE, Seattle, WA 98115.

*Council address:* North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501-2252; telephone: (907) 271-2809.

**FOR FURTHER INFORMATION CONTACT:** Diana Stram, Council staff; telephone: (907) 271-2806.

#### SUPPLEMENTARY INFORMATION:

##### Agenda

Monday, April 15, 2019 to Tuesday, April 16, 2019

The agenda will include a review and discussion of existing salmon bycatch genetics evaluations and discussion of and plan for proposed improvements to facilitate better use of information by stakeholders for bycatch avoidance. The Agenda is subject to change, and the latest version will be posted at <https://meetings.npfmc.org/Meeting/Details/603> prior to the meeting, along with meeting materials.

##### Public Comment

Public comment letters will be accepted and should be submitted either electronically to <https://meetings.npfmc.org/Meeting/Details/603> or through the mail: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501-2252. In-person oral public testimony will be accepted at the discretion of the chair.

##### Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271-2809 at least 7 working days prior to the meeting date.

Dated: March 27, 2019.

**Rey Israel Marquez,**

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

[FR Doc. 2019-06315 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-22-P**

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration**

RIN 0648–XG929

**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 evaluation of joint state/tribal hatchery plans and request for comment.

**SUMMARY:** Notice is hereby given that the Washington Department of Fish and Wildlife, the Muckleshoot Tribe, and the Suquamish Tribe have prepared 10 Hatchery and Genetic Management Plans, to be considered jointly, to NMFS pursuant to the limitation on take prohibitions for actions conducted under Limit 6 of the 4(d) Rule for salmon and steelhead promulgated under the Endangered Species Act (ESA). The plans specify the propagation of four species of salmon and steelhead in the Duwamish/Green River basin of Washington State. This document serves to notify the public of the availability for comment of the proposed evaluation and pending determination of the Secretary of Commerce (Secretary) as to whether implementation of the joint plans will appreciably reduce the likelihood of survival and recovery of ESA-listed Puget Sound Chinook salmon and Puget Sound steelhead.

**DATES:** Comments must be received at the appropriate address (see **ADDRESSES**) no later than 5:00 p.m. Pacific time on May 2, 2019. Comments received after this date may not be accepted.

**ADDRESSES:** Written comments on the proposed evaluation and pending determination should be addressed to Charlene Hurst, NMFS Sustainable Fisheries Division, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97232. Comments may be submitted by email. The mailbox address for providing email comments is: [nmfs.duwamish-green.hatcheries-PEPD@noaa.gov](mailto:nmfs.duwamish-green.hatcheries-PEPD@noaa.gov). Include in the subject line of the email comment the following identifier: Comments on Duwamish/Green River hatchery evaluation. The documents are available on the internet at [www.westcoast.fisheries.noaa.gov](http://www.westcoast.fisheries.noaa.gov). Comments received will also be available for public inspection, by appointment, during normal business hours by calling (503) 230–5409.

**FOR FURTHER INFORMATION CONTACT:** Charlene Hurst at (503) 230–5409 or by email at [Charlene.n.hurst@noaa.gov](mailto:Charlene.n.hurst@noaa.gov).

**SUPPLEMENTARY INFORMATION:****ESA-Listed Species Covered in This Notice**

Chinook salmon (*Oncorhynchus tshawytscha*): threatened, naturally produced and artificially propagated Puget Sound.

Steelhead (*O. mykiss*): threatened, naturally produced and artificially propagated Puget Sound.

**Background**

The Washington Department of Fish and Wildlife, the Muckleshoot Tribe, and Suquamish Tribe have prepared plans for 10 jointly operated hatchery programs in the Duwamish/Green River region. The plans were submitted from April 2013 to June 2017, pursuant to limit 6 of the 4(d) Rule for ESA-listed salmon and steelhead. The hatchery programs release ESA-listed Chinook salmon and winter steelhead and non-listed coho salmon, fall chum salmon, and summer steelhead into the Duwamish/Green River basin and nearby.

As required by the ESA 4(d) Rule (65 FR 42422, July 10, 2000, as updated in 70 FR 37160, June 28, 2005), the Secretary is seeking public comment on his pending determination as to whether the joint plans for hatchery programs in the Duwamish/Green River basin would appreciably reduce the likelihood of survival and recovery of the ESA-listed Puget Sound salmon and steelhead.

**Authority**

Under section 4 of the ESA, the Secretary of Commerce is required to adopt such regulations as he deems necessary and advisable for the conservation of species listed as threatened. The ESA salmon and steelhead 4(d) Rule (65 FR 42422, July 10, 2000, as updated in 70 FR 37160, June 28, 2005) specifies categories of activities that contribute to the conservation of listed salmonids and sets out the criteria for such activities. Limit 6 of the updated 4(d) Rule (50 CFR 223.203(b)(6)) further provides that the prohibitions of paragraph (a) of the updated 4(d) Rule (50 CFR 223.203(a)) do not apply to activities associated with a joint state/tribal artificial propagation plan provided that the joint plan has been determined by NMFS to be in accordance with the ESA salmon and steelhead 4(d) Rule.

Dated: March 27, 2019.

**Angela Somma,**

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–06317 Filed 4–1–19; 8:45 am]

BILLING CODE 3510–22–P

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration**

RIN 0648–XG912

**South Atlantic Fishery Management Council; Public Meetings**

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

**ACTION:** Notice of a public meeting.

**SUMMARY:** The South Atlantic Fishery Management Council (Council) will hold a meeting of its Mackerel and Cobia Advisory Panel (AP) and Cobia Sub-Panel.

**DATES:** The meeting will be held via webinar on April 18, 2019, from 9 a.m. until 12 p.m.

**ADDRESSES:**

*Council address:* South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

*Meeting Address:* The meeting will be held via webinar. The webinar is open to members of the public. Registration is required. Webinar registration, an online public comment form, and briefing book materials will be available two weeks prior to the meeting at: <http://safmc.net/safmc-meetings/current-advisory-panel-meetings/>. Public comments must be received by 12 p.m. on April 18, 2019.

**FOR FURTHER INFORMATION CONTACT:** Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: [kim.iverson@safmc.net](mailto:kim.iverson@safmc.net).

**SUPPLEMENTARY INFORMATION:** The Mackerel Cobia AP and Cobia Sub-Panel will meet jointly via webinar. Agenda items for the AP and Cobia Sub-Panel include: proposed modifications to the commercial trip limit for king mackerel in the Atlantic southern zone during season two (October to the end of February); discussion of recent closures in the commercial Atlantic Spanish mackerel fishery; and modifications to the minimum size limit for Florida east coast zone cobia. The AP and Cobia sub-panel members will discuss these issues and provide recommendations for

Council consideration as appropriate.

### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

**Note:** The times and sequence specified in this agenda are subject to change.

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

Dated: March 28, 2019.

**Tracey L. Thompson,**

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

[FR Doc. 2019-06340 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XG903**

#### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The Mid-Atlantic Fishery Management Council's Surfclam and Ocean Quahog Advisory Panel will hold a public meeting.

**DATES:** The meeting will be held on Friday, April 19, 2019, from 9:30 a.m. until 12:30 p.m.

**ADDRESSES:** The meeting will be held via webinar. Details on the proposed agenda, connection information, and briefing materials will be posted at the MAFMC's website: [www.mafmc.org](http://www.mafmc.org).

*Council address:* Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331; [www.mafmc.org](http://www.mafmc.org).

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is to develop a fishery performance report by the Council's Surfclam and Ocean Quahog Advisory Panel. In addition, the Advisory Panel will be asked to provide feedback on the development of the Council's 2020-24 strategic plan, after reviewing the results of a recent strategic planning stakeholder survey. An agenda and background documents

will be posted at the Council's website ([www.mafmc.org](http://www.mafmc.org)) prior to the meeting.

### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: March 28, 2019.

**Tracey L. Thompson,**

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

[FR Doc. 2019-06339 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XG917**

#### Endangered and Threatened Species; Take of Anadromous Fish

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

**ACTION:** Notice of availability.

**SUMMARY:** Notice is hereby given that NMFS has received seven plans for hatchery operations rearing and releasing Chinook salmon and summer steelhead hatchery programs rearing salmon and steelhead in the Upper Columbia River Basin. The plans describe programs operated by the Washington Department of Fish and Wildlife (WDFW), U.S. Fish and Wildlife Service (USFWS), and Douglas Public Utility District (PUD). The programs are funded by the Douglas PUD, Chelan PUD, Grant PUD, and U.S. Bureau of Reclamation (USBOR). This document serves to notify the public of the availability of these materials, including the draft EA, for review and comment prior to a decision by NMFS on approval of the plan and issuance of the permits.

**DATES:** Comments must be received at the appropriate address (see **ADDRESSES**) no later than 5:00 p.m. Pacific time on May 2, 2019. Comments received after this date may not be considered.

**ADDRESSES:** Written responses to the addendum should be addressed to the NMFS Sustainable Fisheries Division, 1201 NE Lloyd Blvd., Portland, OR 97232. Comments may be submitted by email. The mailbox address for providing email comments is: [Hatcheries.Public.Comment@noaa.gov](mailto:Hatcheries.Public.Comment@noaa.gov). Include in the subject line of the email

comment the following identifier: Comments on Upper Columbia Hatchery programs approvals.

**FOR FURTHER INFORMATION CONTACT:** Emi Kondo at (503) 736-4739 or by email at [emi.kondo@noaa.gov](mailto:emi.kondo@noaa.gov).

**SUPPLEMENTARY INFORMATION:** ESA-Listed Species Covered in This Notice

- Upper Columbia River Spring-run Chinook (*Oncorhynchus tshawytscha*): Endangered, naturally and artificially propagated
- Upper Columbia River Steelhead (*O. mykiss*): Threatened, naturally and artificially propagated

### Background

Section 9 of the Endangered Species Act (ESA) and Federal regulations prohibit the "taking" of a species listed as endangered or threatened. The term "take" is defined under the ESA to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may make exceptions to the take prohibitions in section 9 of the ESA for programs that are approved by NMFS under section 4(d) of the ESA.

The co-managers and funding agencies, including the PUDs, WDFW, USFWS, and USBOR, have submitted hatchery and genetic management plans (HGMP) to NMFS pursuant to sections 4(d), 10(a)(1)(A), and 10(a)(1)(B) of the ESA for hatchery activities in the Upper Columbia River basin. For the programs considered under section 10, the HGMPs serve as permit applications.

The HGMPs describe actions involving hatchery activities (with associated monitoring and evaluation) in the Upper Columbia River basin. The programs are intended to contribute to the survival and recovery of Upper Columbia River Basin steelhead in the Upper Columbia River basin, and to responsibly enhance fishing opportunity on hatchery-origin summer/fall and fall Chinook salmon and steelhead returns.

### Authority

NMFS will evaluate each application, associated documents, and comments submitted thereon to determine whether the applications meet the requirements of section 4(d) of the ESA, Limit 5, and sections 10(a)(1)(A) and 10(a)(1)(B) of ESA. If it is determined that the requirements are met under the sections mentioned above, one HGMP will be approved for the purpose of carrying out the hatchery programs and the relevant section 10 permits will be issued. NMFS will publish a record of its final action in the **Federal Register**.

Dated: March 27, 2019.

**Angela Somma,**

*Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2019-06316 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XG857**

#### Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

**ACTION:** Notice; request for comments.

**SUMMARY:** The Acting Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application from the Coonamessett Farm Foundation contains all of the required information and warrants further consideration. This Exempted Fishing Permit would allow a participating party/charter fishing vessel to temporarily possess undersized black sea bass for tagging and biological sampling purposes. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

**DATES:** Comments must be received on or before April 17, 2019.

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

- *Email:* NMFS.GAR.EFP@noaa.gov.

Include in the subject line "Comments on CFF Black Sea Bass Tagging EFP."

- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on CFF Black Sea Bass Tagging EFP."

**FOR FURTHER INFORMATION CONTACT:** Cynthia Ferrio, Fishery Management Specialist, 978-281-9180, [Cynthia.Ferrio@noaa.gov](mailto:Cynthia.Ferrio@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The Coonamessett Farm Foundation (CFF) submitted a complete application for an Exempted Fishing Permit (EFP) on

February 27, 2019, to conduct fishing activities that the regulations would otherwise restrict. The EFP would authorize a participating vessel to temporarily possess undersize black sea bass while conducting tagging procedures and biological sampling. This research is designed to tag and release black sea bass to study movement patterns, habitat usage, and migratory cycles for up to the 2-year battery life of the telemetry tags.

If approved, this research would be conducted over the course of four 3-day long sampling trips in April and August of 2019 and 2020, for a total of 12 research fishing days. All fishing would be conducted using rod and reel gear on a contracted charter vessel in state and Federal waters off the coasts of Maryland, Virginia, and North Carolina. The exact fishing locations would be determined by the vessel captain, but would be recorded via GPS.

All black sea bass caught on directed research trips under this EFP would be placed in a live well, and the length and sex of each individual would be recorded before tagging. Each black sea bass would then be tagged with an internal anchor spaghetti tag, allowed to recover from the procedure, assessed for barotrauma, and released back into the water using a pressure-activated recompression descending release device. All non-target species would be returned to the water as quickly as possible, and no catch would be retained for sale. CFF personnel would accompany all trips and oversee these research activities.

In addition to the spaghetti tags, 92 black sea bass are expected to be tagged with additional specialty tags/equipment through this project, with the type of specialized tag used and data gathered depending on the size and vigor of each fish. A total of 48 fish will receive acoustic transmitters to record temperature, 40 slightly larger fish (greater than 25 cm) will receive an additional archival tag that records temperature, depth, and conductivity, and four of the largest fish (greater than 46 cm) will be affixed with satellite tags. The satellite tags measure temperature, depth, light level, and geolocation.

CFF is requesting temporary exemptions from the recreational possession limit and minimum size possession restrictions in the Black Sea Bass Fishery Management Plan found at 50 CFR 648.145(a) and § 648.147(b) to sample and tag all black sea bass during these selected fishing trips. Funding for this research has been awarded under a NOAA Chesapeake Bay Fisheries Research grant (NA18NMF4570257).

If approved, CFF may request minor modifications and extensions to the EFP throughout the study period. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: March 28, 2019.

**Alan D. Risenhoover,**

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

[FR Doc. 2019-06368 Filed 4-1-19; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XG923**

#### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The Mid-Atlantic Fishery Management Council's Bluefish Advisory Panel will hold a public meeting.

**DATES:** The meeting will be held on Thursday, April 25, 2019, from 9:30 a.m. to 11 a.m.

**ADDRESSES:** The meeting will be held via webinar with an audio-only connection option. Details on the proposed agenda, connection information, and briefing materials will be posted at the MAFMC's website: [www.mafmc.org](http://www.mafmc.org).

*Council address:* Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331; [www.mafmc.org](http://www.mafmc.org).

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is for the Advisory Panel to provide feedback on the development of the Council's 2020-24 strategic plan, after reviewing the results of a recent strategic planning

stakeholder survey. An agenda and background documents will be posted at the Council's website ([www.mafmc.org](http://www.mafmc.org)) prior to the meeting.

#### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: March 28, 2019.

#### Tracey L. Thompson,

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

[FR Doc. 2019-06342 Filed 4-1-19; 8:45 am]

BILLING CODE 3510-22-P

### DEPARTMENT OF COMMERCE

#### National Oceanic and Atmospheric Administration

RIN 0648-XG924

#### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

**ACTION:** Notice; public meeting.

**SUMMARY:** The Mid-Atlantic Fishery Management Council's Tilefish Advisory Panel will hold a public meeting.

**DATES:** The meeting will be held on Tuesday, April 23, 2019, from 9:30 a.m. to 11 a.m.

**ADDRESSES:** The meeting will be held via webinar with an audio-only connection option. Details on the proposed agenda, connection information, and briefing materials will be posted at the MAFMC's website: [www.mafmc.org](http://www.mafmc.org).

*Council address:* Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331; [www.mafmc.org](http://www.mafmc.org).

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is for the Advisory Panel to provide feedback on the development of the Council's 2020-24 strategic plan, after reviewing the results of a recent strategic planning stakeholder survey. An agenda and background documents will be posted at

the Council's website ([www.mafmc.org](http://www.mafmc.org)) prior to the meeting.

#### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: March 28, 2019.

#### Tracey L. Thompson,

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

[FR Doc. 2019-06343 Filed 4-1-19; 8:45 am]

BILLING CODE 3510-22-P

### DEPARTMENT OF COMMERCE

#### National Oceanic and Atmospheric Administration

RIN 0648-XG922

#### Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The Pacific Fishery Management Council (Pacific Council) will convene a Stock Assessment Review (STAR) Panel meeting to review the 2019 Pacific mackerel stock assessment.

**DATES:** The meeting will be held Tuesday, April 23, through Thursday, April 25, 2019. The meeting will start at 8:30 a.m. PDT on April 23 and 8 a.m. on April 24-25. The meeting will continue until 5 p.m. each day or when business for the day has been completed.

**ADDRESSES:** The meeting will be held in the Pacific Room at the NOAA Southwest Fisheries Science Center, 8901 La Jolla Shores Drive, La Jolla, CA 92037-1508.

*Council address:* Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

**FOR FURTHER INFORMATION CONTACT:** Kerry Griffin, Pacific Council; telephone: (503) 820-2409.

**SUPPLEMENTARY INFORMATION:** The primary purpose of the meeting is to review the 2019 stock assessment for Pacific mackerel, which will be used to set annual harvest specifications and management measures for two fishing years (July 1, 2019 through June 30, 2020, and July 1, 2020 through June 30,

2021). The review panel will consist of three members of the Pacific Council's Scientific and Statistical Committee's Subcommittee on Coastal Pelagic Species (CPS), and two independent experts. Representatives of the Council's CPS Management Team and the CPS Advisory Subpanel will also participate in the review as advisers.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

#### Special Accommodations

The public listening station is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Dale Sweetnam, [dale.sweetnam@noaa.gov](mailto:dale.sweetnam@noaa.gov) at least 10 days prior to the meeting date.

Dated: March 28, 2019.

#### Tracey L. Thompson,

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

[FR Doc. 2019-06341 Filed 4-1-19; 8:45 am]

BILLING CODE 3510-22-P

### DEPARTMENT OF DEFENSE

#### Department of the Army, Corps of Engineers

#### Intent To Prepare a Draft Environmental Impact Statement for the Upper Barataria Basin, LA Study

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers, New Orleans District (USACE) intends to prepare a Draft Integrated Feasibility Report and Environmental Impact Statement (DIFR-EIS) to assess the potential social, economic, and environmental impacts associated with the proposed project titled, Upper Barataria Basin Coastal Feasibility Study. The DIFR-EIS will document the existing condition of environmental resources in and around areas considered for construction, and potential impacts on those resources as

a result of implementing the alternatives.

**DATES:** A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/> and published in the local newspapers no later than 15 days prior to the meeting dates.

**ADDRESSES:** Mr. Scott Wandell, Room 335, CEMVN-PMR-C, 7400 Leake Avenue, New Orleans, LA 70118. *Upper BaratariaFS@usace.army.mil*.

**FOR FURTHER INFORMATION CONTACT:** If you have any questions or comments about the proposed action or would like to be added to the project mailing list please call Mr. Scott Wandell at (504) 862-1798. For additional information, please visit the following <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/>.

**SUPPLEMENTARY INFORMATION:** The lead agency for this proposed action is the USACE. The Louisiana Coastal Protection and Restoration Authority Board is the non-Federal sponsor.

1. *Authority.* The Resolution dated May 6, 1998 of the Committee on Transportation and Infrastructure of the U.S. House of Representatives authorizes a study that will investigate alternatives that may include structural and non-structural measures to address flood risk from tidal surges, coastal storm surges, and heavy rainfall in the area between Bayou Lafourche and the Mississippi River System, from Donaldsonville to the Gulf of Mexico. Notwithstanding Section 105(a) of the Water Resources Development Act of 1986 (33 U.S.C. 2215(a)), which specifies the cost-sharing requirements generally applicable to feasibility studies, Title IV, Division B of the Bipartisan Budget Act of 2018, Public Law 115-123, enacted February 9, 2018 ("BBA 2018"), authorizes the Government to conduct the Study at full Federal expense to the extent that appropriations provided under the Investigations heading of the BBA 2018 are available and used for such purpose. The study phase is 100% federally funded.

2. *Background.* The study area encompasses the Louisiana coastal parishes of St. Charles, Lafourche, Assumption, St. James, St. John the Baptist, and Ascension Parish. A previous feasibility study was begun for the entire basin, but never completed due to the benefit cost ratio. While the previous Donaldsonville to the Gulf Hurricane Protection Feasibility Study

looked at the entire Barataria basin, this study differs from that by focusing solely on the upper basin, while drawing on information from that previous study to inform this feasibility study. The study area has experienced numerous tropical storm events and is vulnerable to loss of life, wildlife, damage to property and infrastructure, and repeated mandatory evacuation costs. The feasibility study will evaluate the proposed alternatives resulting in risk of storm damage reduction to industries and businesses critical to the Nation's economy and protect the health and safety of Louisiana coastal communities in the Upper Barataria Basin.

The study area needs increased resiliency to flood events for the affected communities. In addition, the study area's topography, low elevation, and proximity to the Gulf of Mexico are all contributing factors causing flooding and erosion of wetland systems within the upper basin. Without additional storm damage reduction measures, the people, economy, environment, and cultural heritage of coastal areas in Upper Barataria Basin are at risk from reoccurring damages caused by flooding.

The scoping, public involvement, and interagency coordination processes will help identify and define the range of potential significant issues that will be considered. Important resources and issues evaluated in EIS could include, but are not limited to, the direct, indirect, and cumulative effects on socioeconomic, navigation, wetlands, uplands, aquatic and biological resources, prime and unique farmlands, essential fish habitat, waterfowl, wildlife resources, geology and soils agricultural land and prime and unique farmland; hydrology and hydraulics, threatened and endangered species and their critical habitat, wildlife resources, threatened/endangered species and other protected species of concern, cultural resources, recreation, aesthetics and visual resources, hazardous, toxic and radioactive waste, environmental justice, soils, air quality, and water quality. USACE will also consider issues identified and comments made throughout scoping, public involvement, and interagency coordination.

3. *Alternatives:* The USACE will evaluate a range of alternatives for the proposed action including structural and nonstructural measures. For the reasonable and practicable alternatives, the USACE will fully evaluate them, including the no action alternative. Alternatives may result in avoidance and minimization, and mitigation

measures of impacts to reduce or offset any impacts.

4. *Public Involvement:* Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the NEPA process will be strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially acceptable EIS. Public involvement will include, but is not limited to: Information dissemination; identification of problems, needs and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web.

5. *Scoping:* Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the EIS, will be used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient EIS preparation process; (c) define the issues and alternatives that will be examined in detail in the EIS; and (d) save time in the overall process by helping to ensure that the draft EIS adequately addresses relevant issues. A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/> and published in the local newspapers no later than 15 days prior to the meeting dates.

6. *Coordination:* The USACE will serve as the lead Federal agency in the preparation of the EIS. Other federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the EIS process.

In accordance with Executive Order, 1307, referred to as One Federal Decision (OFD), the USACE and other agencies with environmental review, authorization, or consultation responsibilities for major infrastructure projects should develop a single EIS for such projects, sign a single Record of

Decision (ROD) and issue all necessary authorizations within 90 days thereafter, subject to limited exceptions. An essential element of the OFD framework is the development of a schedule, referred to the "Permitting Timetable," including key milestones critical to completion of the environmental review and issuance of a ROD. Cooperating agencies required by law to develop schedules for environmental review or authorization processes should transmit a summary of such schedules to the lead agency for integration into the Permitting Timetable.

To ensure timely completion of the environmental review and issuance of necessary authorizations, OMB and CEQ recommend the Permitting Timetable for major infrastructure projects provide for environmental review according to the following schedule:

(1) Formal scoping and preparation of a Draft EIS (DEIS) within 14 months, beginning on the date of publication of the NOI to publish an EIS and ending on the date of the Notice of Availability of the DEIS;

(2) Completion of the formal public comment period and development of the Final EIS (FEIS) within eight months of the date of the Notice of Availability of the DEIS; and

(3) Publication of the final ROD within two months of the publication of the Notice of Availability of the FEIS. While the actual schedule for any given project may vary based upon the circumstances of the project and applicable law, agencies should endeavor to meet the two-year goal established in E.O. 13807.

The U.S. Fish and Wildlife Service (Service) will assist in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Start Coordination Act consultation procedures. Other environmental review and consultation requirements for the proposed project include the need for Louisiana Department of Environmental Quality Clean Water Act Section 401 water quality. In addition, because the proposed project may affect federally listed species, the USACE will consult with the Service and the National Marine Fisheries Service (NMFS) in accordance with Endangered Species Act, Section 7. The NMFS will be consulted regarding the effects of this proposed project on Essential Fish Habitat per the Magnuson-Stevens Act. The USACE will also be consulting with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act concerning properties listed, or potentially eligible for listing. The USACE will also be

coordinating with the Louisiana Department of Natural Resources for Coastal Zone Management Consistency per the Coastal Zone Management Act.

7. *Availability:* The Draft EIS (DEIS) is expected to be available for public comment and review no sooner than December 2019. At that time, a 45-day public review period will be provided for individuals and agencies to review and comment on the DEIS. All interested parties are encouraged to respond to this notice and provide a current address if they wish to be notified of the DEIS circulation.

**Brenda S. Bowen,**

*Army Federal Register Liaison Officer.*

[FR Doc. 2019-06359 Filed 4-1-19; 8:45 am]

**BILLING CODE 3720-58-P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### Notice of Intent To Prepare a Draft Environmental Impact Statement for the Lake Pontchartrain and Vicinity General Re-Evaluation Report, Louisiana

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers, New Orleans District (USACE) intends to prepare a Draft Integrated General Re-evaluation Report and Environmental Impact Statement (DGRR-EIS) for the Lake Pontchartrain and Vicinity Coastal Storm Risk Management Project. The study seeks to determine if the work necessary to sustain the 1% level of hurricane storm damage risk reduction is technically feasible, environmentally acceptable, and economically justified.

**ADDRESSES:** Questions or comments about the proposed action or requests to be added to the project mailing list should be directed to Mr. Bradley Drouant, P.E., CEMVN-PMO-L, Room 361, 7400 Leake Avenue, New Orleans, LA 70118; [CEMVN-LPVGRR@usace.army.mil](mailto:CEMVN-LPVGRR@usace.army.mil). For additional information, please visit the following website: <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Bradley Drouant, (504) 862-1516.

**SUPPLEMENTARY INFORMATION:** The lead agency for this proposed action is the USACE. The Louisiana Coastal Protection and Restoration Authority (CPRA) is the non-Federal sponsor.

1. *Authority.* The USACE is preparing the DGRR-EIS under the authority of Section 3017 of WRRDA 2014. Public Law 115-123 (Bipartisan Budget Act of 2018) funded the study as a new start. The study phase is 100% federal funding.

2. *Background.* The devastation to New Orleans and the Gulf Coast from hurricanes Katrina and Rita included the loss of over 1,800 lives, it temporarily and permanently displaced many thousands of residents, and resulted in estimated property damages in excess of \$40 billion in New Orleans and as much as \$100 billion along the Gulf Coast.

After the devastation of the 2005 hurricane season, the U.S. embarked on one of the largest civil works projects ever undertaken, at an estimated cost of \$14 billion. The project included restoration, accelerated construction, improvements, and enhancements of various risk reduction projects within southeastern Louisiana, including the Lake Pontchartrain and Vicinity, Louisiana Project (LPV) and the West Bank and Vicinity, Louisiana Project (WBV), jointly referred to as the Greater New Orleans Hurricane and Storm Damage Risk Reduction System (HSDRRS). The completion of the levees, floodwalls, gates, and pumps that together form the HSDRRS brought 100-year level of hurricane and storm damage risk reduction to the areas within LPV and WBV.

Southeast Louisiana, including the Greater New Orleans area, is generally characterized by weak soils, general subsidence, and the global incidence of sea level rise that will cause levees to require future lifts to sustain performance of the HSDRRS. The HSDRRS project authority did not provide for future lifts. Engineering analysis indicates the HSDRRS will no longer provide 1% level of risk reduction as early as 2023. Absent future levee lifts to offset consolidation, settlement, subsidence, and sea level rise, risk to life and property in the Greater New Orleans area will progressively increase. USACE will notify FEMA once the system no longer provides the 1% level of risk reduction, which may result in the loss of accreditation required for participation in the National Flood Insurance Program.

The DGRR-EIS seeks to determine if the work necessary to sustain the 1% level of risk reduction is technically feasible, environmentally acceptable, and economically justified. The study will also consider other levels of risk reduction. A positive determination

would make construction of future levee lifts eligible for future budget requests.

The significant issues that are likely to be analyzed in depth in the DGRR-EIS include: Climate; relative sea level rise; levee consolidation and compaction; annual probability of failure; life loss; economic damages; geology and soils; hydrology and hydraulics; water resources; forest and wetland resources; uplands; fisheries; essential fish habitat; wildlife; invasive species; threatened and endangered species; cultural and historical resources; scenic and aesthetic resources; recreation; air quality; noise; transportation; population and housing; employment, business, and industrial activity; public facilities and services; community and regional growth; tax revenue and property values; community cohesion; environmental justice; and hazardous, toxic, and radioactive waste.

3. *Alternatives.* The USACE will evaluate a range of alternatives for the proposed action including structural and nonstructural measures. The USACE will fully evaluate reasonable and practicable alternatives, including the no action alternative. Alternatives may result in avoidance, minimization, and mitigation measures to reduce or offset any impacts.

4. *Public Involvement.* Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the NEPA process will be strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially acceptable EIS. Public involvement will include, but is not limited to: Information dissemination; identification of problems, needs, and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder, and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web.

5. *Scoping.* Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the

EIS, will be used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient EIS preparation process; (c) define the issues and alternatives that will be examined in detail in the EIS; and (d) save time in the overall process by helping to ensure that the draft EIS adequately addresses relevant issues.

A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/> and through various advertising avenues widely available to the public no later than 15 days prior to the meeting dates.

6. *Environmental Consultation and Review.* The USACE will serve as the lead Federal agency in the preparation of the DGRR-EIS. Other Federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the study process. The U.S. Fish and Wildlife Service (USFWS) will assist in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Coordination Act consultation procedures. In addition, because the proposed project may affect federally listed species, the USACE will consult with the USFWS and the National Marine Fisheries Service (NMFS) in accordance with the Endangered Species Act, Section 7. The USACE will consult the NMFS regarding the effects of the project on Essential Fish Habitat per the Magnuson-Stevens Fishery Conservation and Management Act. The USACE will also consult with affected Federally Recognized Tribes. Other environmental review and consultation requirements for the proposed project include the need for Louisiana Department of Environmental Quality Clean Water Act Section 401 water quality certification and Clean Air Act coordination. The USACE will also consult with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act concerning properties listed or potentially eligible for listing. The USACE will also coordinate with the Louisiana Department of Natural Resources for coastal zone management consistency per the Coastal Zone Management Act.

7. *Availability.* The USACE currently estimates that the DGRR-EIS will be available for public review and comment in December 2019. At that time, the USACE will provide a 45-day public review period for individuals and agencies to review and comment.

The USACE will notify all interested agencies, organizations, and individuals of the availability of the draft document at that time.

**Brenda S. Bowen,**

*Army Federal Register Liaison Officer.*

[FR Doc. 2019-06354 Filed 4-1-19; 8:45 am]

**BILLING CODE 3720-58-P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### Notice of Intent To Prepare a Draft Environmental Impact Statement for the West Bank and Vicinity General Re-evaluation Report, Louisiana

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers, New Orleans District (USACE) intends to prepare a Draft Integrated General Re-evaluation Report and Environmental Impact Statement (DGRR-EIS) for the West Bank and Vicinity Coastal Storm Risk Management Project. The study seeks to determine if the work necessary to sustain the 1% level of hurricane storm damage risk reduction is technically feasible, environmentally acceptable, and economically justified.

**ADDRESSES:** Questions or comments about the proposed action or requests to be added to the project mailing list should be directed to Mr. Bradley Drouant, P.E., CEMVN-PMO-L, Room 361, 7400 Leake Avenue, New Orleans, LA 70118; [CEMVN-WBVGRR@usace.army.mil](mailto:CEMVN-WBVGRR@usace.army.mil). For additional information, please visit the following website: <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/>.

**FOR FURTHER INFORMATION CONTACT:** Mr. Bradley Drouant, (504) 862-1516.

**SUPPLEMENTARY INFORMATION:** The lead agency for this proposed action is the USACE. The Louisiana Coastal Protection and Restoration Authority (CPRA) is the non-Federal sponsor.

1. *Authority.* The USACE is preparing the DGRR-EIS under the authority of Section 3017 of WRRDA 2014. Public Law 115-123 (Bipartisan Budget Act of 2018) funded the study as a new start. The study phase is 100% federal funding.

2. *Background.* The devastation to New Orleans and the Gulf Coast from Hurricanes Katrina and Rita included the loss of over 1,800 lives, it

temporarily and permanently displaced many thousands of residents, and resulted in estimated property damages in excess of \$40 billion in New Orleans and as much as \$100 billion along the Gulf Coast.

After the devastation of the 2005 hurricane season, the U.S. embarked on one of the largest civil works projects ever undertaken, at an estimated cost of \$14 billion. The project included restoration, accelerated construction, improvements, and enhancements of various risk reduction projects within southeastern Louisiana, including the Lake Pontchartrain and Vicinity, Louisiana Project (LPV) and the West Bank and Vicinity, Louisiana Project (WBV), jointly referred to as the Greater New Orleans Hurricane and Storm Damage Risk Reduction System (HSDRRS). The completion of the levees, floodwalls, gates, and pumps that together form the HSDRRS brought 100-year level of hurricane and storm damage risk reduction to the areas within LPV and WBV.

Southeast Louisiana, including the Greater New Orleans area, is generally characterized by weak soils, general subsidence, and the global incidence of sea level rise that will cause levees to require future lifts to sustain performance of the HSDRRS. The HSDRRS project authority did not provide for future lifts. Engineering analysis indicates the HSDRRS will no longer provide 1% level of risk reduction as early as 2023. Absent future levee lifts to offset consolidation, settlement, subsidence, and sea level rise, risk to life and property in the Greater New Orleans area will progressively increase. USACE will notify FEMA once the system no longer provides the 1% level of risk reduction, which may result in the loss of accreditation required for participation in the National Flood Insurance Program.

The DGRR-EIS seeks to determine if the work necessary to sustain the 1% level of risk reduction is technically feasible, environmentally acceptable, and economically justified. The study will also consider other levels of risk reduction. A positive determination would make construction of future levee lifts eligible for future budget requests.

The significant issues that are likely to be analyzed in depth in the DGRR-EIS include: Climate; relative sea level rise; levee consolidation and compaction; annual probability of failure; life loss; economic damages; geology and soils; hydrology and hydraulics; water resources; forest and wetland resources; uplands; fisheries; essential fish habitat; wildlife; invasive

species; threatened and endangered species; cultural and historical resources; scenic and aesthetic resources; recreation; air quality; noise; transportation; population and housing; employment, business, and industrial activity; public facilities and services; community and regional growth; tax revenue and property values; community cohesion; environmental justice; and hazardous, toxic, and radioactive waste.

**3. Alternatives.** The USACE will evaluate a range of alternatives for the proposed action including structural and nonstructural measures. The USACE will fully evaluate reasonable and practicable alternatives, including the no action alternative. Alternatives may result in avoidance, minimization, and mitigation measures to reduce or offset any impacts.

**4. Public Involvement.** Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the NEPA process will be strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially acceptable EIS. Public involvement will include, but is not limited to: Information dissemination; identification of problems, needs, and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder, and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web.

**5. Scoping.** Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the EIS, will be used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient EIS preparation process; (c) define the issues and alternatives that will be examined in detail in the EIS; and (d) save time in the overall process by helping to ensure that the draft EIS adequately addresses relevant issues.

A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is

anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/> and through various advertising avenues widely available to the public no later than 15 days prior to the meeting dates.

**6. Environmental Consultation and Review.** The USACE will serve as the lead Federal agency in the preparation of the DGRR-EIS. Other Federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the study process. The U.S. Fish and Wildlife Service (USFWS) will assist in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Coordination Act consultation procedures. In addition, because the proposed project may affect federally listed species, the USACE will consult with the USFWS and the National Marine Fisheries Service (NMFS) in accordance with the Endangered Species Act, Section 7. The USACE will consult the NMFS regarding the effects of the project on Essential Fish Habitat per the Magnuson-Stevens Fishery Conservation and Management Act. The USACE will also consult with affected Federally Recognized Tribes. Other environmental review and consultation requirements for the proposed project include the need for Louisiana Department of Environmental Quality Clean Water Act Section 401 water quality certification and Clean Air Act coordination. The USACE will also consult with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act concerning properties listed or potentially eligible for listing. The USACE will also coordinate with the Louisiana Department of Natural Resources for coastal zone management consistency per the Coastal Zone Management Act.

**7. Availability.** The USACE currently estimates that the DGRR-EIS will be available for public review and comment in December 2019. At that time, the USACE will provide a 45-day public review period for individuals and agencies to review and comment. The USACE will notify all interested agencies, organizations, and individuals of the availability of the draft document at that time.

**Brenda S. Bowen,**

*Army Federal Register Liaison Officer.*

[FR Doc. 2019-06352 Filed 4-1-19; 8:45 am]

**BILLING CODE 3720-58-P**

**DEPARTMENT OF DEFENSE****Department of the Army, Corps of Engineers****Notice of Intent To Prepare a Draft Environmental Impact Statement for the South Central Coast Louisiana Flood Risk Management Feasibility Study**

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (USACE), New Orleans District intends to prepare a Draft Integrated Feasibility Report and Environmental Impact Statement (DIFR-EIS) for the Draft Environmental Impact Statement (DEIS) to assess the potential social, economic, and environmental impacts associated with the proposed project titled, South Central Coast Louisiana Flood Risk Management Feasibility Study. The DIFR-EIS documents the existing condition of environmental resources in and around areas considered for development, and potential impacts on those resources as a result of implementing the alternatives.

**ADDRESSES:** Questions or comments about the proposed action or requests to be added to the project mailing list should be directed to Ms. Carrie Schott, CEMVN-PM-B, U.S. Army Corps of Engineers, New Orleans District, 7400 Leake Avenue, New Orleans, LA 70118, email, [Southcentralcoaststudy@usace.army.mil](mailto:Southcentralcoaststudy@usace.army.mil). Comments may also be entered at the following web page: <https://www.mvn.usace.army.mil/South-Central-Coast/>.

**FOR FURTHER INFORMATION CONTACT:** Ms. Carrie Schott, (504) 862-1153.

**SUPPLEMENTARY INFORMATION:** The lead agency for this proposed action is the USACE. The Louisiana Coastal Protection and Restoration Authority (CPRA) is the non-Federal sponsor.

1. *Authority.* The USACE is preparing the DIFR-EIS study under the standing authority of Bipartisan Budget Act of 2018, (Pub. L. 115-123), Division B, Subdivision 1, H. R. 1892-13, Title IV, Corps Of Engineers—Civil, Department Of The Army, Investigations, and H.R. Docket 2767, 20 Sep 2006, Southeast Coastal Louisiana, LA, Resolved by the Committee on Transportation and Infrastructure of the United States House of Representatives. The Bipartisan Budget Act authorizes the USACE proposed South Central Coast Louisiana Flood Protection and Coastal Storm Risk Management Project

planning and potential construction project. The study phase is 100% federally funded.

2. *Background.* The study area encompasses the Louisiana coastal parishes of Iberia, St Mary, and St Martin. The study area has experienced repetitive storm events including Hurricanes Rita, Ike, Gustav, and Andrew, resulting in loss of life, wildlife, and property, and repeated mandatory evacuation costs. This report will present the proposed alternatives resulting in risk of storm damage reduction to industries and businesses critical to the Nation's economy and protect the health and safety of Louisiana coastal communities.

The study area needs increased sustainability and resiliency to flood events for the affected communities. In addition, the study area's topography, low elevation, proximity to the Gulf of Mexico, subsiding lands, and rising seas, are all contributing factors causing coastal flooding, shoreline erosion and loss of wetlands. Without additional storm damage reduction measures, the people, economy, environment, and cultural heritage of coastal areas in South Central Louisiana are at risk from reoccurring damages caused by hurricane storm surge flooding and riverine flooding.

The USACE will analyze numerous issues in the DEIS related to the effects of any proposed storm damage reduction measures. These issues will include, but will not be limited to, the following: Continued wetlands losses impacting migratory species, the ecological nurseries of the Gulf of Mexico, and various commercial and recreational activities.

The USACE will focus their analysis on the following resources: Aesthetics and visual resources, water quality and salinity aquatic resources/wetlands, invasive plant species fish and wildlife resources, threatened/endangered species and other protected species of concern, cultural & historic resources and tribal trust resources, floodplains, hazardous, toxic & radioactive waste, hydrology, land use, navigation and public infrastructure, socio-economics, environmental justice, soils, sustainability, greening and climate change.

3. *Alternatives.* The USACE will evaluate a range of alternatives for the proposed action including structural and nonstructural measures. For the reasonable and practicable alternatives, the USACE will fully evaluate them, including the no action alternative. Alternatives may result in avoidance and minimization, and mitigation

measures of impacts to reduce or offset any impacts.

Structural measures would include wave attenuation measures adjacent to each measure or closer to the coastal shoreline. Structural measures recommended for consideration currently include:

- *Structural Measure 1:* State Alignment A.
  - *Structural Measure 2:* State Alignment B.
  - *Structural Measure 3:* Rail Road Alignment.
  - *Structural Measure 4:* Existing Levee Improvements.
  - *Structural Measure 5:* Ring Levees.
- The USACE is also considering nonstructural measures. These include:
- *Non-structural Measure 1:* Buyouts.
  - *Non-structural Measure 2:* Wet proofing
  - *Non-structural Measure 3:* Dry proofing.

4. *Public Involvement.* Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the NEPA process is strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially acceptable EIS. Public involvement includes, but is not limited to: Information dissemination; identification of problems, needs, and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder, and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web.

5. *Scoping.* Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the EIS, will be used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient EIS preparation process; (c) define the issues and alternatives examined in detail in the EIS; and (d) save time in the overall process by helping to ensure the draft EIS adequately addresses relevant issues.

All interested parties are invited to comment at this time, and anyone interested in the DIFR–DEIS should request to be included on the distribution list. The scoping period will extend for 45 days after the date of this Notice of Intent publication. Comments should be as specific as possible. Additional public involvement will be sought through the implementation of the public involvement plan and the agency coordination team. Comments may be mailed, emailed or entered at: <https://www.mvn.usace.army.mil/South-Central-Coast/>.

A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/South-Central-Coast/> and through various advertising avenues widely available to the public no later than 15 days prior to the meeting dates.

6. *Environmental Consultation and Review.* The USACE will serve as the lead Federal agency in the preparation of the DIFR–DEIS. Other Federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the study process. The U.S. Fish and Wildlife Service (USFWS) will assist in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Coordination Act consultation procedures. In addition, because the proposed project may affect federally listed species, the USACE will consult with the USFWS and the National Marine Fisheries Service (NMFS) in accordance with the Endangered Species Act, Section 7. The USACE will consult the NMFS regarding the effects of the project on Essential Fish Habitat per the Magnuson-Stevens Fishery Conservation and Management Act. The USACE will consult with affected Federally Recognized Tribes. Other environmental review and consultation requirements for the proposed project include the need for Louisiana Department of Environmental Quality Clean Water Act Section 401 water quality certification and Clean Air Act coordination. The USACE will consult with the State Historic Preservation Officer under National Historic Preservation Act, Section 106, concerning properties listed or potentially eligible for listing. The USACE will coordinate with the Louisiana Department of Natural Resources for coastal zone management consistency per the Coastal Zone Management Act.

7. *Availability.* The USACE currently estimates the DIFR–DEIS will be available for public review and comment in December 2019. At that time, the USACE will provide a 45-day public review period for individuals and agencies to review and comment. The USACE will notify all interested agencies, organizations, and individuals of the availability of the draft document at that time.

**Brenda S. Bowen,**

*Army Federal Register Liaison Officer.*

[FR Doc. 2019–06355 Filed 4–1–19; 8:45 am]

**BILLING CODE 3720–58–P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### Intent To Prepare a Draft Environmental Impact Statement for the Amite River and Tributaries-East of the Mississippi River, Louisiana, Flood Risk Management Feasibility Study

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of intent.

**SUMMARY:** Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers, New Orleans District (USACE) intends to prepare a Draft Integrated Feasibility Report and Environmental Impact Statement (DIFR–EIS) to assess the potential social, economic, and environmental impacts associated with the proposed project titled, “Amite River and Tributaries—East of the Mississippi River, Louisiana, Flood Risk Management Feasibility Study.” The DIFR–EIS will document the existing conditions of environmental resources in and around areas considered for construction, and potential impacts on those resources as a result of implementing the alternatives.

**DATES:** A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/> and published in the local newspapers no later than 15 days prior to the meeting dates.

**ADDRESSES:** Ms. Kaitlyn Carriere, CEMVN–PMR, Room 331, 7400 Leake Avenue, New Orleans, LA 70118. [AmiteFS@usace.army.mil](mailto:AmiteFS@usace.army.mil).

**FOR FURTHER INFORMATION CONTACT:** If you have questions or comments about the proposed action or would like to be

added to the project mailing list, please call Ms. Kaitlyn Carriere at (504) 862–1798. For additional information, please visit the following <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/>.

**SUPPLEMENTARY INFORMATION:** The lead agency for this proposed action is the USACE. Louisiana Department of Transportation and Development (LDOTD) is the non-Federal sponsor.

1. *Authority.* The USACE is preparing the DIFR–EIS study under the standing authority of Bipartisan Budget Act of 2018, (Pub. L. 115–123), Division B, Subdivision 1, H. R. 1892–13, Title IV, Corps Of Engineers—Civil, Department Of The Army, Investigations. The Bipartisan Budget Act authorizes the USACE proposed Amite River and Tributaries—East of the Mississippi River, Louisiana, Flood Risk Management Feasibility Study planning and potential construction project. The study phase is 100% federal funding.

2. *Background.* The study area, which includes the Amite River Basin, encompasses an area of approximately 3,450 square miles consisting of 8 Louisiana parishes (East Feliciana, St. Helena, East Baton Rouge, Livingston, Iberville, Ascension, St. James, and St. John the Baptist), Maurepas Lake, and 4 Mississippi counties (Amite, Wilkinson, Franklin, and Lincoln). Over three-fourths of the study area lies in the parishes of southeastern Louisiana, located east of the Mississippi River and north of Lake Maurepas. The upper one-fourth of the study area’s drainage area lies in the southwestern Mississippi counties.

The Amite River and its tributaries has caused flood damages to industrial, commercial, agricultural facilities, and residential and nonresidential structures. As recently as August 2016, the President issued disaster declarations for parishes in the Amite River Basin due to impacts from “The Great Flood of 2016”. The flood was responsible for 13 deaths and the rescue of at least 19,000 people. The study area experienced historic flooding to thousands of homes and businesses and impacts to the Nation’s critical infrastructure because both the I–10 and I–12 transportation system were shutdown for days. Major urban centers in the basin saw significant flooding well outside of normal flood stages.

The Amite River Basin primarily has flooding from two different sources. The Upper Basin flooding is caused from headwater flooding from rainfall events. The lower basin flooding is caused by a combination of drainage from headwaters and backwater flooding

from tides and wind setup. Critical infrastructure throughout the region, includes the I-10 and I-12 transportation system, government facilities, and schools are expected to have increased risk of damage from rainfall damage from rainfall events as a result of climate change.

The USACE will focus their analysis on the following resources as applicable: Aesthetics and visual resources, water quality, aquatic resources/wetlands, fish and wildlife resources, threatened/endangered species and other protected species of concern, cultural & historic resources and tribal trust resources, floodplains, hazardous, toxic & radioactive waste, hydrology, land use, navigation and public infrastructure, socio-economics, environmental justice and soils.

3. *Alternatives.* The USACE will evaluate a range of alternatives for the proposed action including structural and nonstructural measures. For the reasonable and practicable alternatives, the USACE will fully evaluate them, including the no action alternative. Alternatives may result in avoidance and minimization, and mitigation measures of impacts to reduce or offset any impacts.

4. *Public Involvement.* Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the environmental decision making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the NEPA process will be strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, and socially acceptable EIS. Public involvement will include, but is not limited to: Information dissemination; identification of problems, needs and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder and advisory groups consultation and meetings; and making the EIS and supporting information readily available in conveniently located places, such as libraries and on the world wide web.

5. *Scoping.* Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the EIS, will be used to: (a) identify the affected public and agency concerns; (b)

facilitate an efficient EIS preparation process; (c) define the issues and alternatives that will be examined in detail in the EIS; and (d) save time in the overall process by helping to ensure that the draft EIS adequately addresses relevant issues. A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the project website, <https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/> and published in the local newspapers no later than 15 days prior to the meeting dates.

6. *Coordination.* The USACE will serve as the lead Federal agency in the preparation of the EIS. Other federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the EIS process.

In accordance with Executive order, 1307, referred to as One Federal Decision (OFD), the USACE and other agencies with environmental review, authorization, or consultation responsibilities for major infrastructure projects should develop a single EIS for such projects, sign a single Record of Decision (ROD) and issue all necessary authorizations within 90 days thereafter, subject to limited exceptions. An essential element of the OFD framework is the development of a schedule, referred to the "Permitting Timetable," including key milestones critical to completion of the environmental review and issuance of a ROD. Cooperating agencies required by law to develop schedules for environmental review or authorization processes should transmit a summary of such schedules to the lead agency for integration into the Permitting Timetable.

To ensure timely completion of the environmental review and issuance of necessary authorizations, OMB and CEQ recommend the Permitting Timetable for major infrastructure projects provide for environmental review according to the following schedule:

(1) Formal scoping and preparation of a Draft EIS (DEIS) within 14 months, beginning on the date of publication of the NOI to publish an EIS and ending on the date of the Notice of Availability of the DEIS;

(2) Completion of the formal public comment period and development of the Final EIS (FEIS) within eight months of the date of the Notice of Availability of the DEIS; and

(3) Publication of the final ROD within two months of the publication of the Notice of Availability of the FEIS.

While the actual schedule for any given project may vary based upon the circumstances of the project and applicable law, agencies should

endeavor to meet the two-year goal established in E.O. 13807.

The U.S. Fish and Wildlife Service (Service) will assist in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Start Coordination Act consultation procedures. Other environmental review and consultation requirements for the proposed project include the need for Louisiana Department of Environmental Quality Clean Water Act Section 401 water quality. In addition, because the proposed project may affect federally listed species, the USACE will consult with the Service and the National Marine Fisheries Service (NMFS) in accordance with Endangered Species Act, Section 7. The NMFS will be consulted regarding the effects of this proposed project on Essential Fish Habitat per the Magnuson-Stevens Act. The USACE will also be consulting with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act concerning properties listed, or potentially eligible for listing. The USACE will also be coordinating with the Louisiana Department of Natural Resources for Coastal Zone Management Consistency per the Coastal Zone Management Act.

7. *Availability.* The Draft EIS (DEIS) is expected to be available for public comment and review no sooner than December 2019. At that time, a 45-day public review period will be provided for individuals and agencies to review and comment on the DEIS. All interested parties are encouraged to respond to this notice and provide a current address if they wish to be notified of the DEIS circulation.

**Brenda S. Bowen,**

*Army Federal Register Liaison Officer.*

[FR Doc. 2019-06353 Filed 4-1-19; 8:45 am]

**BILLING CODE 3720-58-P**

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

#### Filings Instituting Proceedings

*Docket Number:* PR17-54-000.

*Applicants:* B&W Pipeline, LLC.

*Description:* Supplemental Information/Request of B&W Pipeline, LLC under PR17-54. Stipulation and Agreement.

*Filed Date:* 3/21/19.

*Accession Number:* 201903215143.  
*Comments/Protests Due:* 5 p.m. ET 4/11/19.

*Docket Number:* PR19–32–001.  
*Applicants:* Southern California Gas Company.

*Description:* Tariff filing per 284.123(b),(e)+(g): Offshore Delivery Service Rate Revision—March 2019 to be effective 11/28/2018;

*Filed Date:* 3/22/19.  
*Accession Number:* 201903225001.  
*Comments Due:* 5 p.m. ET 4/12/19.  
284.123(g) Protests Due: 5 p.m. ET 5/21/19.

*Docket Number:* PR19–51–000.  
*Applicants:* Kansas Gas Service, A Division of ONE Gas, Inc.

*Description:* Tariff filing per 284.123(b),(e)+(g): Revision to Statement of Operating Conditions to be effective 2/5/2019;

*Filed Date:* 3/21/19.  
*Accession Number:* 201903215167.  
*Comments Due:* 5 p.m. ET 4/11/19.  
284.123(g) Protests Due: 5 p.m. ET 5/20/19.

*Docket Numbers:* RP19–892–000.  
*Applicants:* Southern Natural Gas Company, L.L.C.

*Description:* § 4(d) Rate Filing: SCANA Negotiated Rate to be effective 5/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5052.  
*Comments Due:* 5 p.m. ET 4/8/19.  
*Docket Numbers:* RP19–893–000.

*Applicants:* Algonquin Gas Transmission, LLC.  
*Description:* § 4(d) Rate Filing: Negotiated Rate—Boston 510798 to SFE 798877 eff 4–1–19 to be effective 4/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5063.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–894–000.  
*Applicants:* Alliance Pipeline L.P.  
*Description:* Compliance filing Alliance Pipeline Order 587–Y (Docket RM96–1–041) Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5077.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–895–000.  
*Applicants:* Iroquois Gas Transmission System, L.P.

*Description:* Compliance filing 032619 FERC Order 587–Y (NAESB) Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5092.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–896–000.  
*Applicants:* Young Gas Storage Company, Ltd.

*Description:* Compliance filing Initial Settlement Implementation Compliance Filing to be effective 1/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5111.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–897–000.  
*Applicants:* Texas Eastern Transmission, LP.

*Description:* § 4(d) Rate Filing: Negotiated Rate—MC Global 911524 releases eff 4–1–19 to be effective 4/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5112.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–898–000.  
*Applicants:* Greylock Pipeline, LLC.

*Description:* Compliance filing NASB compliance to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5128.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–899–000.  
*Applicants:* Rover Pipeline LLC.

*Description:* Compliance filing NAESB Version 3.1 Compliance to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5140.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–900–000.  
*Applicants:* Gulf States Transmission LLC.

*Description:* Compliance filing NAESB Version 3.1 Compliance to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5141.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–901–000.  
*Applicants:* Lake Charles LNG Company, LLC.

*Description:* Compliance filing NAESB Version 3.1 Compliance to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5142.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–902–000.  
*Applicants:* Millennium Pipeline Company, LLC.

*Description:* § 4(d) Rate Filing: Negotiated Rate Svc Agmt Filing—DTE to be effective 4/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5164.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–903–000.  
*Applicants:* El Paso Natural Gas Company, L.L.C.

*Description:* § 4(d) Rate Filing: Negotiated Rate Agreements Filing (Targa United Dairymen) to be effective 4/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5225.

*Comments Due:* 5 p.m. ET 4/8/19.  
*Docket Numbers:* RP19–904–000.  
*Applicants:* Freebird Gas Storage, L.L.C.

*Description:* Compliance filing FERC Order No. 587–Y Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5228.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–905–000.  
*Applicants:* Dominion Energy Cove Point LNG, LP.

*Description:* § 4(d) Rate Filing: DECP—Rate Schedule LTS to be effective 4/26/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5230.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–906–000.  
*Applicants:* Caledonia Energy Partners, L.L.C.

*Description:* Compliance filing FERC Order No. 587–Y Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5231.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–907–000.  
*Applicants:* East Cheyenne Gas Storage, LLC.

*Description:* Compliance filing FERC Order No. 587–Y Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5232.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–908–000.  
*Applicants:* High Island Offshore System, L.L.C.

*Description:* Compliance filing Order No. 587–Y Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5233.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–909–000.  
*Applicants:* Mississippi Hub, LLC.

*Description:* Compliance filing FERC Order No. 587–Y Compliance Filing to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5235.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–910–000.  
*Applicants:* Gulf Shore Energy Partners, LP.

*Description:* Compliance filing Order No. 587–Y & #40;NAESB&#41; to be effective 8/1/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5236.  
*Comments Due:* 5 p.m. ET 4/8/19.

*Docket Numbers:* RP19–911–000.  
*Applicants:* Rockies Express Pipeline LLC.

*Description:* Annual Incidental Purchases and Sales Report of Rockies Express Pipeline LLC under RP19–911.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5250.  
*Comments Due:* 5 p.m. ET 4/8/19.  
*Docket Numbers:* RP19–912–000.  
*Applicants:* Trailblazer Pipeline Company LLC.

*Description:* Annual Incidental Purchases and Sales Report of Trailblazer Pipeline Company LLC under RP19–912.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5251.  
*Comments Due:* 5 p.m. ET 4/8/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 26, 2019.

**Nathaniel J. Davis, Sr.,**  
 Deputy Secretary.

[FR Doc. 2019–06380 Filed 4–1–19; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

#### Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER16–1609–002.  
*Applicants:* ID SOLAR 1, LLC.  
*Description:* Supplement to October 22, 2019 ID SOLAR 1, LLC tariff filing (Notice of Change in Status).

*Filed Date:* 3/12/19.  
*Accession Number:* 20190312–5227.  
*Comments Due:* 5 p.m. ET 4/2/19.  
*Docket Numbers:* ER17–532–001.  
*Applicants:* PPA Grand Johanna LLC.  
*Description:* Supplement to February 19, 2019 Notice of Non-Material Change in Status of PPA Grand Johanna LLC.  
*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5178.  
*Comments Due:* 5 p.m. ET 4/16/19.

*Docket Numbers:* ER19–1398–000.  
*Applicants:* Ameresco, Inc.  
*Description:* Petition Of Ameresco, Inc. For Limited Waiver of Tariff Submission Deadline for Project Electrical Data Sheets.

*Filed Date:* 3/21/19.  
*Accession Number:* 20190321–5064.  
*Comments Due:* 5 p.m. ET 4/4/19.  
*Docket Numbers:* ER19–1404–000.  
*Applicants:* PJM Capacity Suppliers.  
*Description:* Request for Limited Waiver, et al. of the PJM Capacity Suppliers.

*Filed Date:* 3/21/19.  
*Accession Number:* 20190321–5165.  
*Comments Due:* 5 p.m. ET 4/2/19.  
*Docket Numbers:* ER19–1445–000.  
*Applicants:* Midcontinent Independent System Operator, Inc.  
*Description:* § 205(d) Rate Filing: 2019–03–26 SA 3290 Vectren-Republic T–T to be effective 3/26/2019.

*Filed Date:* 3/26/19.  
*Accession Number:* 20190326–5234.  
*Comments Due:* 5 p.m. ET 4/16/19.  
*Docket Numbers:* ER19–1446–000.  
*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: Attachment P Revisions to Modify Submission Time for Daily Non-Firm Service to be effective 5/29/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5027.  
*Comments Due:* 5 p.m. ET 4/17/19.  
*Docket Numbers:* ER19–1447–000.  
*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* § 205(d) Rate Filing: 2019–03–27 SA 3012 Wisconsin Power & Light-ATC 2nd Rev GIA (J390 J760) to be effective 3/13/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5034.  
*Comments Due:* 5 p.m. ET 4/17/19.  
*Docket Numbers:* ER19–1448–000.  
*Applicants:* Entergy Services, LLC.  
*Description:* Tariff Cancellation:

Entergy Services, Inc. to be effective 1/1/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5036.  
*Comments Due:* 5 p.m. ET 4/17/19.  
*Docket Numbers:* ER19–1449–000.  
*Applicants:* Midcontinent Independent System Operator, Inc., MidAmerican Energy Company.

*Description:* § 205(d) Rate Filing: 2019–03–27 SA 3281 MidAmerican—Outlaw Wind Project E&P (J476) to be effective 3/12/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5058.  
*Comments Due:* 5 p.m. ET 4/17/19.  
*Docket Numbers:* ER19–1450–000.  
*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Original ICSA, SA No. 5312; Queue No. AC1–165 to be effective 2/25/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5076.  
*Comments Due:* 5 p.m. ET 4/17/19.

*Docket Numbers:* ER19–1451–000.  
*Applicants:* PJM Interconnection, L.L.C.

*Description:* Tariff Cancellation: Notice of Cancellation of WMPA/SA No. 5052, Queue No. AD1–028 to be effective 4/23/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5080.  
*Comments Due:* 5 p.m. ET 4/17/19.

*Docket Numbers:* ER19–1452–000.  
*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* § 205(d) Rate Filing: 2019–03–27\_SA 2465 Rock Aetna Power-Northern States Power 2nd Revised GIA (G621) to be effective 3/13/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5081.  
*Comments Due:* 5 p.m. ET 4/17/19.

*Docket Numbers:* ER19–1453–000.  
*Applicants:* West Penn Power Company, PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: West Penn Power Company submits IA SA No. 4119 to be effective 5/25/2019.

*Filed Date:* 3/27/19.  
*Accession Number:* 20190327–5091.  
*Comments Due:* 5 p.m. ET 4/17/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 26, 2019.

**Nathaniel J. Davis, Sr.,**  
 Deputy Secretary.

[FR Doc. 2019–06379 Filed 4–1–19; 8:45 am]

**BILLING CODE 6717–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

[DA 19-193]

### Media Bureau Lifts LPTV and TV Translator Application Filing Freezes Effective April 18, 2019

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** This document announces that, effective April 18, 2019, the Media Bureau is lifting the displacement and digital companion channel application filing freezes related to low power television and TV translator stations.

**DATES:** The filing freezes will be lifted effective April 18, 2019.

**FOR FURTHER INFORMATION CONTACT:** Shaun Maher, Video Division, Media Bureau, Federal Communications Commission, *Shaun.Maher@fcc.gov*, (202) 418-2324.

**SUPPLEMENTARY INFORMATION:** The Media Bureau announces that, effective April 18, 2019, it is lifting the displacement and digital companion channel application filing freezes related to low power television and TV translator stations (LPTV/translator stations). These freezes were imposed to preserve channels for the window for LPTV/translator stations displaced by the Incentive Auction to file displacement applications (Special Displacement Window or Window). The displacement freeze was temporarily lifted to accommodate the filing of displacement applications by licensed LPTV/translator stations which were displaced by Incentive Auction matters in the Special Displacement Window. With completion of the Special Displacement Window on June 1, 2018, and post-Window settlement opportunity on January 10, 2019, the Media Bureau deems it appropriate to now lift these filing freezes. Interested parties may resume filing of the below-referenced applications on a first-come, first-serve basis on April 18, 2019.

Displacement Applications. The freeze on the filing of displacement applications, enacted in 2014, is lifted effective April 18, 2019.

Digital Companion Channels. The freeze on the filing of applications for digital companion channels, enacted in 2017, is lifted effective April 18, 2019.

The freeze on the filing of applications for new LPTV/translator digital stations and major changes remains in effect.

This action is taken by the Chief, Media Bureau pursuant to authority delegated by 47 CFR 0.283 of the Commission's rules.

Federal Communications Commission.

**Barbara Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 2019-06362 Filed 4-1-19; 8:45 am]

**BILLING CODE 6712-01-P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meeting

**FEDERAL REGISTER CITATION NOTICE OF PREVIOUS ANNOUNCEMENT:** 84 FR 10516  
**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:** Tuesday, March 26, 2019 at 10:00 a.m.

**CHANGES IN THE MEETING:** This meeting was continued on Thursday, March 28, 2019.

This meeting also discussed: Matters relating to internal personnel decisions, or internal rules and practices.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

\* \* \* \* \*

**CONTACT FOR MORE INFORMATION:** Judith Ingram, Press Officer, Telephone: (202) 694-1220.

**Laura E. Sinram,**

*Deputy Secretary of the Commission.*

[FR Doc. 2019-06433 Filed 3-29-19; 11:15 am]

**BILLING CODE 6715-01-P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested

persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 26, 2019.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *FSB Financial Corp., Valliant, Oklahoma*; to become a bank holding company by acquiring 100 percent of the voting shares of First State Bank, Valliant, Oklahoma.

Board of Governors of the Federal Reserve System, March 27, 2019.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2019-06287 Filed 4-1-19; 8:45 am]

**BILLING CODE P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act ("Act") (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 16, 2019.

A. *Federal Reserve Bank of Kansas City* (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *The Oliver Tracy Kelly 1991 Revocable Trust dated August 29, 1991 and Polly Kelly, Tulsa, Oklahoma, as trustee, Joy Kelly, Tulsa, Oklahoma, Faith Kelly, Edmond, Oklahoma, William Marshall Clune, Edmond,*

Oklahoma, Hope Dobias, Denver, Colorado, Cloie Dobias, Oxford, Ohio, Elleon Dobias, Chicago, Illinois, and the Kelly Brothers, A Business Trust, Bristow, Oklahoma; to be approved as members of the Kelly-Clune-Dobias family group, and thereby acquire voting shares of Spirit BankCorp, Inc., Bristow, Oklahoma, and thereby acquire shares of SpiritBank, Tulsa, Oklahoma.

B. *Federal Reserve Bank of New York* (Ivan Hurwitz, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001. Comments can also be sent electronically to

*Comments.applications@ny.frb.org*:

1. *Alberto Joseph Safra, David Joseph Safra and Esther Safra Dayan, Sao Palo, Brazil and Jacob Joseph Safra, Geneva, Switzerland*; to acquire voting shares of SNBNY Holdings Limited, Gibraltar, Gibraltar and thereby indirectly acquire Safra National Bank of New York, New York, New York.

Board of Governors of the Federal Reserve System, March 27, 2019.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2019-06286 Filed 4-1-19; 8:45 am]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[30Day-19-18AJA]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled Assessment of Environmental Health and Land Reuse Certification Training to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 27, 2018 to obtain comments from the public and affected agencies. ATSDR did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR 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

Assessment of Environmental Health and Land Reuse Certification Training—New—Agency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH/ATSDR), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) Clearance for a new Information Collection Request (ICR) entitled "Assessment of Environmental Health and Land Reuse Certification Training." The specific activities of the ICR request is to collect participant feedback on the environmental health land reuse certificate course content developed by ATSDR and its collaborator. This information collection is funded through a contract with the National Environmental Health Association (NEHA), number 200-2013-57475.

Due to the prevalence of potentially contaminated land reuse sites such as brownfields, ATSDR is partnering with NEHA to build capacity among health agency staff through the certificate. The certificate program/training modules focus on increasing skills in Land Reuse

and Redevelopment through the integration of Epidemiology, Risk Assessment, Risk Communication, and Toxicology concepts and resources. This certificate training will be hosted on ATSDR's website as well as linked by NEHA's existing online Learning Management System, which hosts a variety of certificate and credentialing courses. In addition, CDC's Training and Communication Online (TCEO) (0920-0017; expiration 6/30/2019), a system that provides access to CDC educational activities for continuing education (CE), will register participants and provide continuing education credits for the certificate course.

The purpose of the information collection is to access the registration data and evaluate the impact of the certification program. The certification is geared to meet the following objectives:

- Increase participant awareness and knowledge of environmental health and land reuse;
- Increase skills and capacity of participants to engage in environmental health and land reuse work; and
- Assess participant feedback and assessment of their own increased awareness, skills, and knowledge in environmental health and land reuse.

ATSDR will request registration data from TCEO and use this data to conduct one time follow-up to assess the impact of participating in the certification, such as increased capacity of environmental health professionals to perform their work. Ultimately, ATSDR is interested in long-term benefits of the certification, such as state health partners engaging more frequently in land reuse and redevelopment projects.

Through this information collection, ATSDR would like to determine the utility and effectiveness of the certification course content. Subsequently, ATSDR will analyze the data provided by NEHA regarding participants' job titles (e.g. LHD staff, environmental consultant, or other), the pre- and post-testing built-in components of the certification course, and a one-time collection of feedback (e.g. within 6-11 months after participation) on use of the certification materials and resources to build their capacity and skills in environmental health and land reuse.

The respondents for the certification course will largely be environmental professionals; students of environmental science, public health, or planning; and local or state health agency professionals. ATSDR may perform descriptive analysis to characterize certification course participants (e.g. by job title) and to summarize their

feedback on the course content and effectiveness. In summary, the feedback information will help ATSDR determine impacts of the certification course in building capacity and skills in environmental health and land reuse. Without this information, ATSDR will not be able to assess the effectiveness of the certification in terms of building participants' capacity in environmental health and land reuse activities. In addition, ATSDR can generalize feedback from course participants to

create new materials that can support additional capacity-building for health agencies to increase their involvement in environmental health and land reuse activities.

This one time follow up information collection will occur through support of collaborators National Environmental Health Association (NEHA) as well as other partners (e.g. tribal entities) who will provide participant names and emails for users who have taken the training in order to conduct a one time follow up survey. ATSDR will collect

feedback data about the certification course. The feedback data will center around participant's assessment of their own potentially increased skills in environmental health and land reuse as a result of the certification and use of subsequent certification components. Participation in this proposed information collection is completely voluntary. There is no cost to respondents other than their time. The total time burden is estimated to be 67 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Environmental health professionals and graduate students.	Follow-up Survey .....	200	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019-06302 Filed 4-1-19; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0853]

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 Asthma Information Reporting System (AIRS) 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 December 6, 2018 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](mailto: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

Asthma Information and Reporting System (AIRS) (OMB Control No. 0920-0853, Expiration Date: 06/30/2019)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 1999, the CDC began its National Asthma Control Program (NACP), a public health approach to address the burden of asthma. The program supports the goals and objectives of "Healthy People 2020" for asthma and is based on the public health principles of surveillance, partnerships, interventions, and evaluation. The CDC requests a 12-month approval to revise the "Asthma Information Reporting System (AIRS)" (OMB Control No. 0920-0853, Expiration Date 6/30/2019). Specifically, CDC seeks to make the following changes:

- Increase the number of awardees from 23 to 25.
- Increase the requested burden hours from 82 to 89.
- Increase the number of optional performance measures (PMs) and decrease the number of required PMs, while still maintaining a total of 18 PMs.

- Update the instructions for the data collection instruments to reflect the optional status of 5 of the 18 PMs and to clarify instructions that were commonly misinterpreted.

- Update the Emergency Department Data and Hospital Discharge Data reporting forms to include example data submission templates for each awardee. Add a tab labeled "Technical Notes" within the Excel reporting form to collect clarifying information about the data from each awardee.

- Add examples of Emergency Department Data and Hospital Discharge Data reporting forms to provide clarity on how data should be reported within the forms.

- Update respondent costs to reflect current wage data from 2017.

The 12-month approval will allow CDC to continue to monitor states' program planning and delivery of public health activities and the programs' collaboration with health care systems for the remainder of the fifth and final year of cooperative agreement EH14-1404 (program period: September 2014—August 2019), and the third and final year of cooperative agreement EH16-1606 (program period: September 2016—August 2019).

The goal of this data collection is to provide NCEH with routine information about the activities and performance of the state and territorial awardees funded under the NACP through an annual reporting system. NACP requires awardees to report activities related to partnerships, infrastructure, evaluation and interventions to monitor the state programs' performance in reducing the burden of asthma. AIRS also includes

two forms to collect aggregate ED and HD data from awardees.

AIRS was first approved by OMB in 2010 to collect data in a web-based system to monitor and guide participating state health departments. Since implementation in 2010, AIRS and the technical assistance provided by CDC staff have provided states with uniform data reporting methods and linkages to other states' asthma program information and resources. Thus, AIRS has saved state resources and staff time when asthma programs embark on asthma activities similar to those done elsewhere.

In the past three years, AIRS data were used to:

- Serve as a resource to NCEH when addressing congressional, departmental and institutional inquiries.
- Help the branch align its current interventions with CDC goals and allowed the monitoring of progress toward these goals.

- Allow the NACP and the state asthma programs to make more informed decisions about activities to achieve objectives.

- Facilitate communication about interventions across states, and enable inquiries regarding interventions by populations with a disproportionate burden, age groups, geographic areas and other variables of interest.

- Provide feedback to the grantees about their performance relative to others through the distribution of two written reports and several presentations (webinar and in-person) summarizing the results.

- Customize and provide technical assistance and support materials to address implementation challenges.

There will be no cost to respondents other than their time to complete the three AIRS spreadsheets annually. The estimated annualized burden hours are 89.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Asthma Program Awardees ..	AIRS Performance Measures Reporting Spreadsheets.	25 .....	1	150/60
	AIRS Emergency Department Visits Reporting Form.	25 .....	1	30/60
	AIRS Hospital Discharge Reporting Forms.	25 .....	1	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. 2019-06304 Filed 4-1-19; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-19-19LX]

**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 Assessment of Clinical and Microbiologic Outcomes in Patients Infected with *Shigella* with Decreased Susceptibility to Ciprofloxacin and Azithromycin through a Prospective Case-Control Study in California 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 29, 2018 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](mailto: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**

Assessment of Clinical and Microbiologic Outcomes in Patients Infected with *Shigella* with Decreased Susceptibility to Ciprofloxacin and Azithromycin through a Prospective Case-Control Study in California—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

A broad 60-day notice for this project entitled “Applied Research to Address Emerging Public Health priorities” was published on May 29, 2018. This project is part of a series of CDC research projects funded under that Broad Agency Announcement.

Multidrug-resistant *Shigella* is a public health problem in the U.S, including California. Resistance to first line drugs (azithromycin and ciprofloxacin) limits treatment options and may be associated with worse patient outcomes. In 2017, the Centers for Disease Control and Prevention (CDC) reported an increase in *Shigella* isolates with ciprofloxacin minimum inhibitory concentration (MIC) range=0.12–1.0 µg/mL. In 2018, this was updated (<https://emergency.cdc.gov/han/han00411.asp>) and confirmed a continued increase in such isolates.

While current Clinical and Laboratory Standards Institute (CLSI) criteria categorize *Shigella* isolates that fall within this range as susceptible, these strains often harbor a quinolone resistance gene, which may be associated with decreased susceptibility to ciprofloxacin. Little is known about the clinical implications of infection with *Shigella* with ciprofloxacin MICs in the range of 0.12–1 µg/mL; including whether treatment with a fluoroquinolone is associated with a worse clinical outcome for the patient, or will result in prolonged shedding and further reduction in ciprofloxacin susceptibility. In addition, CLSI has not established clinical breakpoints for azithromycin, making treatment decisions challenging for clinicians when managing patients with multidrug-resistant *Shigella* infections. Systematically collected data regarding the clinical and microbiologic outcomes of patients infected with *Shigella* with ciprofloxacin MIC 0.12–1 µg/mL or that fall above the epidemiologic cutoffs for azithromycin (≥16 µg/mL for *S. flexneri*, ≥32 µg/mL for *S. sonnei*) are needed to inform clinical breakpoints.

The primary objectives of the study are to: (1) Estimate the proportion of California *Shigella* isolates with a ciprofloxacin MIC range of 0.12–1.0 µg/mL and the proportion of *Shigella*

isolates that fall above the epidemiologic cutoffs for azithromycin; (2) determine whether patients who were infected with *Shigella* with a ciprofloxacin MIC range of 0.12–1.0 µg/mL and treated with a fluoroquinolone (and thus have decreased susceptibility to ciprofloxacin, or DSC *Shigella*) have worse clinical and microbiologic outcomes than patients who were infected with *Shigella* with a ciprofloxacin MIC <0.12 µg/mL and were also treated with a fluoroquinolone; (3) systematically describe the clinical outcomes of patients infected with *Shigella* that fall above the epidemiologic cutoffs for azithromycin (referred to as decreased susceptibility to azithromycin, DSA *Shigella*); and (4) explore microbiologic features including antimicrobial susceptibility testing (AST) patterns and WGS of *Shigella* isolates with DSC and DSA. Results of this investigation will provide data that may inform CLSI breakpoints and shape public health recommendations on management and prevention of DSC and DSA *Shigella* infections.

CDC is seeking one year of OMB approval. There is no cost to respondents other than the time to participate. Total estimated annual burden is 878 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
<i>Shigella</i> cases and controls .....	Case Interview Form Initial .....	230 .....	1	45/60
	Case Interview Form Second .....	230 .....	1	45/60
	Symptom Log Form .....	230 .....	1	30/60
	Stool collection and submission initial.	230 .....	1	90/60
	Stool collection and submission second.	144 .....	1	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. 2019-06303 Filed 4-1-19; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60 Day-19-19ACB; Docket No. CDC-2019-0021]

**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 “Drug Overdose Surveillance and Epidemiology (DOSE).” This new data collection effort is an essential component toward reducing the opioid crisis, one of HHS Department’s top priorities. DOSE data is critical to our

ability to rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level.

**DATES:** CDC must receive written comments on or before June 3, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2019–0021 by any of the following methods:

- *Federal eRulemaking Portal:*

*Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Jeffery 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**

Drug Overdose Surveillance and Epidemiology (DOSE)—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

The rapid increase in opioid overdose deaths since 2013, numerous severe fentanyl and fentanyl analog outbreaks occurring since 2015 across the United States, and the declaration of the opioid overdose epidemic as a national public health emergency on October 26, 2017 have highlighted the urgent need to rapidly establish and enhance timely surveillance of suspected drug, opioid, heroin, and stimulant overdoses. These data are critical to inform timely local, state, and regional responses, especially to acute and/or widespread multi-state outbreaks.

This new data collection effort is an essential component toward reducing the opioid crisis, one of DHHS's top priorities. DOSE data is critical to our ability to rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level. This will be accomplished by standardizing and enhancing sharing of existing ED data locally collected by 52 health departments (all 50 state health departments, the health department of Puerto Rico, and the health department of the District of Columbia) with CDC. In addition, CDC leadership

communicates with HHS on an ongoing basis, and this data is part of its request to better monitor, plan, and implement programs to prevent overdose and reduce subsequent harms.

DOSE proposes to fund 52 health departments (50 state health departments, the health department of Puerto Rico and the health department of the District of Columbia) to rapidly share existing ED data on counts of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses using two standard data forms (*i.e.*, the Rapid ED overdose data form and the ED discharge overdose data form) and standard CDC case definitions.

The system will leverage ED syndromic data and hospital discharge data on ED visits already routinely collected by state and territorial health departments. No new data will be systematically collected from EDs, and health departments will be reimbursed by CDC for the burden related to sharing ED data with CDC. The 52 funded health departments will rapidly share existing ED data with CDC on a monthly basis using the Rapid ED overdose data form and standard CDC case definitions. Data may come from different local ED data systems, but is expected to cover at least 75% of ED visits in the jurisdiction (*e.g.*, state).

CDC will require all participating health departments to provide counts of ED visits involving suspected drug, opioid, heroin, and stimulant overdoses by county, age group, sex, and time (*i.e.*, month and year) in a standardized manner using the Rapid ED overdose data form, which is an Excel data template. This form also collects data quality indicators such as percent of ED visits missing data on key variables (*i.e.*, metadata). In order to assess and improve rapid ED data sharing, all 52 participating health departments will also be asked to share counts of ED visits involving suspected drug, opioid, heroin and stimulant overdoses by county, age group, sex, and time (*i.e.*, month and year) from more finalized hospital discharge files, the current surveillance standard. The data will be shared with CDC on a quarterly or yearly basis using a standardized Excel data form, the ED discharge overdose data form, and standard CDC case definitions. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	No. of respondents	Total no. of responses per respondent	Average burden per response (hours)	Total annual burden (hours)
State health departments, the DC health department and PR health department.	Rapid ED overdose data form .....	28	12	3	1,088
Jurisdictions sharing case-level ED data with CDC through the NSSP BioSense (OMB #0920–0824).	Rapid ED overdose data form .....	24	12	0.5	144
State health departments, the DC health department and PR health department.	ED discharge overdose data form ...	26	4	3	312
State health departments, the DC health department and PR health department.	ED discharge overdose data form ...	26	1	3	78
<b>Total</b> .....	.....	.....	.....	.....	<b>1,542</b>

**Jeffrey M. Zirger,**  
*Lead, Information Collection Review Office,  
 Office of Scientific Integrity, Office of Science,  
 Centers for Disease Control and Prevention.*  
 [FR Doc. 2019–06305 Filed 4–1–19; 8:45 am]  
**BILLING CODE 4163–19–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day–19–19ABV; Docket No. CDC–2019–0019]

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Information Collection on Soil-transmitted Helminth Infections in Alabama and Mississippi. CDC requests OMB approval to collect information on prevalence and distribution of soil-transmitted helminth infections and potential risk factors.

**DATES:** CDC must receive written comments on or before June 3, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2019–0019 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov.* Follow the instructions for submitting comments.

- **Mail:** Jeffrey M. Zirger, Lead, 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: 404–639–7118. Email: *omb@cdc.gov.*

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To

comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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**

Investigation on soil-transmitted helminth infections in Alabama and Mississippi—New—Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

Soil-transmitted helminths (STH) are intestinal worms transmitted through contaminated soil. They include roundworms (*Ascaris lumbricoides*), whipworms (*Trichuris trichiura*), hookworms (*Ancylostoma duodenale* and *Necator americanus*) and the worm *Strongyloides stercoralis*. These infections were widespread across the American South through the early 20th

century, yet despite the historically high burden of STH infections in these endemic areas of the United States, few resources have been devoted to surveillance, prevention, and treatment of STH infections in recent years and they are missed by routine information collection systems. As a result, the current prevalence of STH infections in previously endemic areas is unknown, but socioeconomic and environmental conditions favorable to ongoing transmission persist in areas of the south, including Alabama and Mississippi. Collecting this data, along with biological specimens to document infection, is critical to determine the prevalence of STH infections, their distribution, and risk factors associated

with infection. This data will be used to inform the development and implementation of effective and sustainable prevention and control measures in affected areas.

The core data elements were developed with input from community advocates, and local, state, and federal public health and environmental health partners in both Alabama and Mississippi. The questionnaires have been designed for self-completion by respondents. The data that are collected will be pooled and analyzed by university partners and CDC, to generate hypotheses about potential risk factors for infection.

CDC requests OMB approval to collect critical information, not available otherwise, on the prevalence and

distribution of disease and on risk factors, knowledge, attitudes and/or practices related to STH infections among residents in at-risk areas in Alabama and Mississippi. This information is critical for planning and implementation of disease prevention and control strategies targeting STH infections in the southeastern United States.

This data collection is not expected to entail substantial burden for respondents. The estimated total annualized burden associated with this data collection is 220 hours (approximately 958 individuals interviewed × 10 minutes/response). There will be 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	Average burden per response (in hrs.)	Total burden (in hrs.)
Individuals .....	Questionnaire—Alabama .....	600	1	10/60	100
Individuals .....	Questionnaire—Mississippi .....	358	1	10/60	60
Individuals .....	Anthropometric data—Mississippi ....	358	1	10/60	60
Total .....	.....	.....	.....	.....	220

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019-06306 Filed 4-1-19; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-19TG; Docket No. CDC-2019-0010]

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 information collection, as required by the Paperwork Reduction Act of 1995. This notice invites

comment on the Million Hearts® Hospital/Health System Recognition Program that recognizes institutions working systematically to improve the cardiovascular health of the population and communities they serve.

DATES: CDC must receive written comments on or before June 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0010 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

Million Hearts® Hospital/Health System Recognition Program—New ICR—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Heart disease, stroke and other cardiovascular diseases (CVDs) kill over 800,000 Americans each year, accounting for one in every three deaths. CVD is the nation’s number one killer among both men and women and the leading cause of health disparities. Million Hearts®, a national, public-private initiative co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), was established to address this issue.

Whether migrating towards value-based reimbursement or simply striving for a significant impact in reducing the devastation of heart attacks and strokes, clinical organizations are positioned to improve the health of the population they serve by implementing high-impact, evidence-based strategies. Achieving a Million Hearts® Hospital/Health System designation signals a

commitment to not only clinical quality, but population health overall.

The Program will recognize institutions that are working to systematically improve the cardiovascular health of the population and communities that they serve by implementing strategies under the Million Hearts® priority areas of keeping people healthy, optimizing care, improving outcomes for priority populations, and innovating for health. CDC anticipates that applicants will range from health systems with multiple hospitals, hospitals with and without ambulatory medical practices, and medical practices not affiliated with hospitals. Any clinical entity whose leaders consider it eligible may apply. Recognition can be achieved by a robust commitment to implement specific strategies, by implementing specific strategies, and most importantly by achieving specific outcomes. Applicants will complete the Million Hearts® Hospital/Health System Recognition Program application, indicating the areas in which they are committing to implement Million Hearts® strategies; areas in which they have implemented key strategies; and those strategies for which they have achieved outcomes/ results.

Applicants must address a minimum of one strategy in at least three of the four priority areas (Keeping People Healthy, Optimizing Care, Improving Outcomes for Priority Populations and Innovating for Health) that are outlined in the application. However, they are encouraged to target as many strategies as is appropriate for their institution. Applicants will be subject to a background check.

The Million Hearts® Hospitals/Health System designation is intended to convey that the institution is committed to preventing heart attacks and strokes by a combination of efforts that are about Keeping People Healthy,

Optimizing Care, Improving Outcomes for Priority Populations and Innovating for Health. All applicants with reported outcomes and a select number of those who are committing to implement or are implementing Million Hearts® strategies, will be asked to participate in a semi-structured, qualitative interview. The purpose of the interview is to obtain in-depth contextual information about the Million Hearts® strategies and facilitators used to achieve improved cardiovascular outcomes among the applicant’s patient population. Applicants with reported outcomes will receive increased recognition from Million Hearts® by having their success stories highlighted on the Million Hearts® website, e-newsletter, etc.

After the Million Hearts® Hospital/Health System Recognition Program launches, the web-based application will be open throughout the year and applications will be reviewed on a quarterly basis and recognized within six months of acceptable review. CDC estimates that information will be collected from up to 100 applicants per year. The overall goal of the Million Hearts® initiative is to prevent one million heart attacks and strokes. Promoting evidence-based strategies that prevent CVD is one focus of the initiative.

CDC will use the information collected through the Million Hearts® Hospital/Health System Recognition Program to increase widespread attention on successful and sustainable implementation strategies, improve understanding of these strategies at the practice level, bring visibility to organizations that commit, implement, or have implemented Million Hearts® strategies and motivate other hospitals and health systems to strengthen their efforts to address CVD. OMB approval is requested for three years. Participation is voluntarily 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.)
Medical & Health Service Service Manager.	Recognition Program Application .....	100	1	160/60	267
Medical & Health Service Manager ..	Interview Guide .....	60	1	30/60	30
Total .....	.....	.....	.....	.....	297

Jeffrey M. Zirger,

Lead, Information Collection Review Office,  
Office of Scientific Integrity, Office of Science,  
Centers for Disease Control and Prevention.

[FR Doc. 2019-06311 Filed 4-1-19; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-19-19VJ; Docket No. CDC-2019-0013]

#### 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 Childcare Survey of Activity and Wellness (C-SAW) Pilot Study. The pilot study will determine the current practices and policies of early care and education (ECE) providers in four states around nutrition, physical activity, and wellness and will inform the development of a potential national surveillance system.

**DATES:** CDC must receive written comments on or before June 3, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019-0013 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.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](https://www.regulations.gov).

**Please note:** Submit all comments through the Federal eRulemaking portal ([regulations.gov](https://www.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](mailto: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 Childcare Survey of Activity and Wellness (C-SAW) Pilot Study—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC)

#### Background and Brief Description

The Centers for Disease Control and Prevention (CDC) works to promote

optimal nutrition, physical activity, and wellness in early care and education (ECE) facilities for children 0-5 years of age. Consistent with this mission, and with clear evidence that ECE facilities can impact the habits and preferences of young children, this survey is necessary to better understand ECE center practices related to nutrition, physical activity, and wellness. These critical data are used to effectively inform state and national programs.

Data collected from this pilot survey will be used to understand the current practices of ECE centers in a representative sample in four states. This initial C-SAW will establish baseline measures of the prevalence of specific practices related to nutrition, physical activity, and wellness in a standard way across states. This baseline will also allow CDC and state partners to better understand ECE center needs and provide opportunities for collaboration and areas for improvement at the state and national levels. Second, the survey will be used to inform the development of a potential national surveillance system enabling states and CDC to track changes over time and obtain data to guide the planning, implementation, and evaluation of national and state obesity prevention efforts.

A sample of approximately 1,266 ECE centers across four states will be selected to participate in this one-time data collection effort. However, it is estimated that approximately 10% of the original sample will be out of business or otherwise ineligible yielding an actual sample of 1,140 ECEs to be recruited. Each center will receive a recruitment letter introducing the survey, explaining its objectives and the importance of their participation, and instructions for completing the survey. It is anticipated that most responses will be submitted through the web. However, paper surveys will be available upon request. Approximately two weeks after the initial recruitment letter is mailed, all sampled centers will receive a reminder postcard. Approximately four weeks after the initial recruitment letter is mailed, nonrespondents will be sent another letter along with a hardcopy of the questionnaire. It is also anticipated that the response rate will be approximately 55% based on a review of recent surveys of child care centers conducted by the Federal government. Thus, we anticipate the number of completed surveys to be 627. CDC requests approval for an estimated 409 Burden Hours. Participation in this study is completely voluntary and there are no costs to the respondent 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)
ECE Director or Administrator .....	Recruitment Letter .....	1,140	1	5/60	95
ECE Director or Administrator .....	Web/Mail Survey .....	627	1	30/60	314
Total .....	.....	.....	.....	.....	409

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

[FR Doc. 2019-06312 Filed 4-1-19; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-0803]

**Advisory Committee; Technical Electronic Product Radiation Safety Standards Committee; Renewal**

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

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Technical Electronic Product Radiation Safety Standards Committee (Committee) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until December 24, 2020.

**DATES:** Authority for the Technical Electronic Product Radiation Safety Standards Committee would have expired on December 24, 2018, unless the Commissioner formally determined that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993-0002, 301-796-6875, [Patricio.Garcia@fda.hhs.gov](mailto:Patricio.Garcia@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Committee. The Committee is a non-discretionary Federal advisory

committee established to provide advice and consultation to the Commissioner. The Commissioner of Food and Drugs is charged with the administration of the Radiation Control for Health and Safety Act of 1968. This act creates the Committee and requires the Commissioner to consult with the Committee before prescribing standards for radiation emissions from electronic products. This Committee provides advice and consultation to the Commissioner of Food and Drugs on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products and may recommend electronic product radiation safety standards to the Commissioner for consideration.

The Committee shall consist of a core of 15 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of science or engineering applicable to electronic product radiation safety. Members will be invited to serve for overlapping terms of up to 4 years. Terms of more than 2 years are contingent upon the renewal of the Committee by appropriate action prior to its expiration. The core of voting members will include five members selected from governmental agencies, including State and Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor. A quorum shall consist of 10 members, of which at least 3 shall be from the general public, 3 from the government agencies, and 3 from the affected industries.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/default.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light

of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Commissioner of Food and Drugs.*

[FR Doc. 2019-06360 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-P-2754]

**Determination That ONFI (Clobazam) Tablets, 5 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that ONFI (clobazam) tablets, 5 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to the drug product, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6206, Silver Spring, MD 20993-0002, 240-402-0978.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate

versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ONFI (clobazam) tablets, 5 mg, is the subject of NDA 202067, held by Lundbeck Pharmaceuticals, LLC, and initially approved on October 21, 2011. ONFI is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age or older.

In a letter dated November 2, 2012, Lundbeck Pharmaceuticals, LLC, notified FDA that ONFI (clobazam) tablets, 5 mg, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Ascend Laboratories, LLC, submitted a citizen petition dated July 17, 2018 (Docket No. FDA-2018-P-2754), under 21 CFR 10.30, requesting that the Agency determine whether ONFI (clobazam) tablets, 5 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under

§ 314.161 that ONFI (clobazam) tablets, 5 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ONFI (clobazam) tablets, 5 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ONFI (clobazam) tablets, 5 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ONFI (clobazam) tablets, 5 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06381 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-0430]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a new collection of information entitled “Generic Clearance for Quick Turnaround Testing of Communication Effectiveness.”

**DATES:** Submit either electronic or written comments on the collection of information by June 3, 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 June 3, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 3, 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–0430 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness.” 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:** Ila S. Mizrahi, 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](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Generic Clearance for Quick Turnaround Testing of Communication Effectiveness**

*OMB Control Number 0910–New*

This notice announces the FDA information collection request to OMB for approval of a generic clearance that will allow FDA to use quick turnaround surveys, focus groups, and in-depth interviews collected from consumers and other stakeholders to communicate FDA issues of immediate and important public health significance. For example, these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, cosmetics, or

animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information to help ensure its messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

FDA will only submit individual collections for approval under this generic clearance if they meet the following conditions:

- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both the participants and the Federal Government;
- The collections are noncontroversial;
- Personally identifiable information (PII) is collected only to the extent necessary<sup>1</sup> and is not retained;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;<sup>2</sup> and
- Information gathered will yield qualitative findings; the collections will not be designed or used as though the results are generalizable to the population of study.

If these conditions are not met, FDA will submit an information collection request to OMB for approval through the normal PRA process.

To obtain approval for an individual collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (e.g., a copy of the survey, focus group moderator guide, or in-depth interviewing guide).

Individual collections will also undergo review by FDA senior leadership in the Center for Food Safety and Applied Nutrition, PRA specialists, and an institutional review board.

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed.

<sup>1</sup> For example, collections that collect PII to provide remuneration for participants of focus groups, in-depth interviews, and cognitive laboratory studies will be submitted under this request. All privacy act requirements will be met.

<sup>2</sup> As defined in OMB and Agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.”

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-depth Interviews, Cognitive Interviews Screener	45	1	45	0.083 (5 minutes) .....	4
In-depth Interviews, Cognitive Interviews .....	9	1	9	1 .....	9
In-depth Interviews Screener .....	900	1	900	0.083 (5 minutes) .....	75
In-depth Interviews .....	180	1	180	1 .....	180
Survey Cognitive Interviews Screener .....	45	1	45	0.083 (5 minutes) .....	4
Survey Cognitive Interviews .....	9	1	9	1 .....	9
Pretest survey screener .....	750	1	750	0.083 (5 minutes) .....	62.25
Pretest survey .....	150	1	150	0.25 (15 minutes) .....	38
Self-Administered Surveys—Study Screener .....	75,000	1	75,000	0.083 (5 minutes) .....	6,225
Self-Administered Surveys .....	15,000	1	15,000	0.25 (15 minutes) .....	3,750
Focus Group/Small Group, Cognitive Groups Screener.	180	1	180	0.083 (5 minutes) .....	15
Focus Group/Small Group, Cognitive Groups .....	60	1	60	1.5 (90 minutes) .....	90
Focus Group/Small Group Participant Screening ...	720	1	720	0.083 (5 minutes) .....	60
Focus Group/Small Group Discussion .....	240	1	240	1.5 (90 minutes) .....	360
<b>Total</b> .....					<b>10,881.25</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This is a new collection of information whose total estimated annual burden is 10,881.25 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new individual survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: March 28, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06365 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-1107]

#### Youth Tobacco Cessation: Science and Treatment Strategies; Public Scientific Workshop; Request for Comments

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

**ACTION:** Notice of public scientific workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public scientific workshop entitled “Youth Tobacco Cessation: Science and Treatment Strategies.” The purpose of the workshop is to discuss the unique

challenges associated with youth tobacco addiction and cessation, and the current science regarding youth tobacco use and addiction as well as treatment strategies to support youth tobacco cessation.

**DATES:** The public scientific workshop will be held on May 15, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this workshop by May 31, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public scientific workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Entrance for public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, 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 May 31, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 31, 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–1107 for “Youth Tobacco Cessation: Science and Treatment Strategies.” 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:**

Allison Hoffman, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3138, Silver Spring, MD 20993, 301–796–9203, [OMPTFeedback@fda.hhs.gov](mailto:OMPTFeedback@fda.hhs.gov) (please use “Youth Tobacco workshop” as the subject line).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Nearly all tobacco product use begins during youth and young adulthood (Ref. 1). In 2017–2018, there was an alarming increase in tobacco product use among adolescents, primarily driven by e-cigarette use (Refs. 2 and 3). Youth tobacco use raises a number of health concerns including risk of addiction to nicotine early on in life, potential harm to the developing adolescent brain, and exposure to chemicals, including carbonyl compounds and volatile organic compounds known to have adverse health effects. The full range of possible health effects is not yet completely understood (Ref. 4).

On April 24, 2018, FDA announced its Youth Tobacco Prevention Plan.<sup>1</sup> This plan focuses on three key strategies: Prevention of youth access to tobacco products, curbing the marketing of tobacco products aimed at youth, and educating teens about the dangers of using any tobacco products, as well as educating retailers about their key role in protecting youth.<sup>2</sup> FDA recently launched an expansion of its “The Real Cost” campaign to educate youth on the dangers of e-cigarette use<sup>3</sup> and increased enforcement actions to address this critically important public health concern.<sup>4</sup>

In addition to the prevention of initiation, which will be the cornerstone of any successful effort to curb youth tobacco use, FDA is also exploring additional approaches to address this issue. On January 18, 2019, FDA held an open public hearing entitled “Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies,”<sup>5</sup> which requested information on the potential role of drug therapies to support cessation and the issues impacting the development of such therapies for

youth. FDA appreciates that youth have unique challenges when it comes to addiction and cessation, and that they may respond differently to treatments as compared to adults.

The challenge of developing evidence in pediatric populations exists in many therapeutic areas. FDA is committed to addressing this issue. Therefore, FDA has issued grants to the Institute for Advanced Clinical Trials for Children (I–ACT for Children) and the Duke Clinical Research Institute (DCRI) to establish a Global Pediatric Clinical Trials Network to facilitate clinical trials of new drugs and devices for children. As a part of this work, I–ACT for Children and DCRI are hosting this public scientific workshop, in collaboration with FDA, to facilitate the development of evidence to support youth tobacco cessation efforts, and will result in a written report. This scientific workshop intends to explore many of the scientific issues brought up during the recent public hearing on this topic.

**II. Topics for Discussion at the Public Scientific Workshop**

This public scientific workshop will gather scientific information and stimulate discussion about the current science regarding youth tobacco use and addiction, and treatment strategies to support youth tobacco cessation with a focus on e-cigarette cessation. This is because e-cigarettes are the tobacco products most commonly used by youth (Ref. 5) and there continues to be a rampant rise in use. According to data from the FDA/CDC 2018 National Youth Tobacco Survey, more than 3.6 million middle and high school students were current e-cigarettes users in 2018, representing a substantial increase of more than 1.5 million students in one year (Ref. 3). Furthermore, data recently published in JAMA Network Open showed that youth e-cigarette users are more likely to transition to conventional cigarettes, as compared to non-users (Ref. 6). The workshop is intended to explore the challenges of treating youth tobacco addiction and promoting cessation. In particular, the workshop will highlight differences in treatment strategies needed in youth as opposed to adults. The workshop will include presentations and panel discussions regarding substantive scientific information specifically relating to the unique factors impacting youth tobacco use and addiction and challenges associated with youth tobacco cessation. Topics to be addressed include (1) the basic science of tobacco addiction in adolescents, (2) current state of behavioral and pharmacotherapy cessation strategies in adolescents (*e.g.*,

<sup>1</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm>.

<sup>2</sup> <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm>.

<sup>3</sup> <https://www.fda.gov/tobaccoproducts/publichealtheducation/publiceducationcampaigns/therealcostcampaign/default.htm>.

<sup>4</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm>.

<sup>5</sup> <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm620744.htm>

clinical trial experience to date, use of technology and social media, impact of social factors), and (3) the development of strategies to generate robust evidence to address youth tobacco cessation (e.g., clinical trial design, measures of adolescent addiction, selection of endpoints, subpopulation and comorbidity considerations, and patient recruitment and retention). Presenters may include, but are not limited to, staff from FDA's Center for Tobacco Products, FDA's Center for Drug Evaluation and Research, industry, and academia. There will be opportunities for the audience to ask questions during this workshop.

### III. Participating in the Public Scientific Workshop

**Registration:** To register for the public scientific workshop, please visit the following website by May 13, 2019: <https://youth-tobacco-cessation.eventbrite.com>. Please provide complete contact information for each attendee, including name, affiliation, and email address.

Registration is free and based on space availability. Persons interested in attending this workshop must register by May 13, 2019, 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. You may choose not to register, however seating is limited, and space will be available on a first-come, first-served basis.

If you need special accommodations because of a disability, please contact Allison Hoffman (see **FOR FURTHER INFORMATION CONTACT**) no later than May 8, 2019.

Persons attending FDA's meetings are advised that the Agency is not responsible for providing access to electrical outlets.

**Streaming Webcast of the Public Scientific Workshop:** This public scientific workshop will also be webcast. To register for the streaming webcast of the workshop, please visit the following website by May 13, 2019: <https://youth-tobacco-cessation.eventbrite.com>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document

publishes in the **Federal Register**, but websites are subject to change over time.

### IV. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Department of Health and Human Services (2014). "The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, 2014." Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. (Available at: <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.)
2. Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al. (2018). "Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011–2018." *MMWR Morbidity and Mortality Weekly Report*, 67:1276–1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5>. (Available at: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm>.)
3. Gentzke, A.S., M. Creamer, K.A. Cullen, et al. (2019). "Vital Signs: Tobacco Product Use Among Middle and High School Students—United States, 2011–2018." *MMWR Morbidity and Mortality Weekly Report*, 68:157–164. DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>. (Available at: <https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm>.)
4. U.S. Department of Health and Human Services (2016). "E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General." Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. (Available at: [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf).)
5. Wang, T.W., A. Gentzke, S. Sharapova, et al. (2018). "Tobacco Product Use Among Middle and High School Students—United States, 2011–2017." *Morbidity and Mortality Weekly Report (MMWR)* 67:629–633. DOI: <https://doi.org/10.15585/mmwr.mm6722a3> (Available at <https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>.)
6. Berry, K.M., J.L. Fetterman, E.J. Benjamin, et al. (2019). "Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths."

JAMA Netw Open 2(2):e187794. DOI: <https://doi.org/10.1001/jamanetworkopen.2018.7794> (Available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.)

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019–06323 Filed 4–1–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–2032]

#### Limited Population Pathway for Antibacterial and Antifungal Drugs; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Limited Population Pathway for Antibacterial and Antifungal Drugs." The purpose of the meeting is to provide a public forum for FDA to listen to comments on the draft guidance for industry, "Limited Population Pathway for Antibacterial and Antifungal Drugs," that was published in the **Federal Register** on June 13, 2018. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before we finish work on the final version of the guidance.

**DATES:** The public meeting will be held on July 12, 2019, from 9 a.m. to 3 p.m. Eastern Time. Submit either electronic or written comments by August 12, 2019, to ensure that the Agency considers your comments on the draft guidance before it finishes work on the final version of the guidance. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

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-2018-D-2032 for "Limited Population Pathway for Antibacterial and Antifungal Drugs." 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)).

**FOR FURTHER INFORMATION CONTACT:** Sarah Walinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993-0002, [sarah.walinsky@fda.hhs.gov](mailto:sarah.walinsky@fda.hhs.gov), 240-402-4075; 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

In the **Federal Register** for June 13, 2018 (83 FR 27616), FDA announced the availability of a draft guidance for industry entitled "Limited Population Pathway for Antibacterial and Antifungal Drugs."<sup>1</sup> This draft guidance

<sup>1</sup> <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm610498.pdf>.

provides information on the implementation of section 506(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(h), added by section 3042 of the 21st Century Cures Act, which established the limited population pathway for antibacterial and antifungal drugs (LPAD pathway). This draft guidance is intended to assist sponsors in the development of certain new antibacterial and antifungal drugs for approval under the LPAD pathway. This draft guidance also is intended to assist sponsors in developing labeling, including prescribing information, patient labeling, and carton/container labeling, that incorporates certain statements required by section 506(h) of the FD&C Act. The LPAD pathway is intended to encourage the development of certain antibacterial and antifungal drugs for limited and specific populations of patients to help address the critical public health and patient care concern that has resulted from the current decline in antibacterial and antifungal drug research and development as serious antibacterial and antifungal drug-resistant infections increase.

FDA received numerous comments on the draft guidance from a diverse group of stakeholders. FDA also received requests for listening meetings with FDA to provide feedback concerning the draft guidance on the LPAD pathway. In view of these requests and to promote transparency, FDA will hold a public meeting at which stakeholders may present or comment on the draft guidance.

The format of the meeting involves presentations from the public. The Agency will not be inviting specific presenters; rather, with this document, FDA is soliciting presentations from interested stakeholders. FDA also invites interested persons to submit written comments to the docket established with the publication of the draft guidance on the LPAD pathway. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before it finishes work on the final version of the guidance. Submit either electronic or written comments by August 12, 2019, to ensure that the Agency considers your comments on this draft before it finishes work on the final version of the guidance.

##### II. Topics for Discussion at the Public Meeting

FDA is holding a public meeting to receive information and comments concerning the draft guidance on the LPAD pathway from a broad group of

stakeholders, including patients, researchers, healthcare providers, manufacturers, interested industry, professional organizations, and the public. The Agency has determined that a public meeting is the most appropriate way to ensure public engagement on the draft guidance. FDA welcomes any relevant information that stakeholders wish to share.

### III. Participating in the Public Meeting

**Registration:** To register for the public meeting, please visit the following website: [https://fdalimitedpoppathwayantibacterial\\_antifungal.eventbrite.com](https://fdalimitedpoppathwayantibacterial_antifungal.eventbrite.com) by July 1, 2019, at 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public meeting must register by July 1, 2019, at 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8:15 a.m. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact Sarah Walinsky (see **FOR FURTHER INFORMATION CONTACT**) no later than July 1, 2019, at 11:59 p.m. Eastern Time.

**Requests for Oral Presentations:** During online registration you may indicate which topic(s) you wish to address, and an approximate desired length of your presentation, so that FDA can consider this information in organizing the presentations. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to present. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will select and notify participants. All requests to make oral presentations must be received by the close of registration on July 1, 2019, at 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to the Sarah Walinsky

(see **FOR FURTHER INFORMATION CONTACT**) no later than 12 p.m. Eastern Time July 8, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Presenters are encouraged to submit a copy of their presentation and related written material to the docket (see **ADDRESSES**) in advance of the public meeting.

**Streaming Webcast of the public meeting:** This public meeting will also be webcast via <https://collaboration.fda.gov/lppaadpm0719>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm631810.htm>.

Dated: March 28, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06390 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-1215]

#### Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice, establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to collect comments related to the post-marketing pediatric-focused safety reviews of products posted between October 12, 2018, and April 1, 2019, on FDA's website but not presented at the April 8, 2019, Pediatric Advisory Committee (PAC) meeting.

These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

**DATES:** Submit either electronic or written comments by April 15, 2019.

**ADDRESSES:** FDA is establishing a docket for public comment on this document. The docket number is FDA-2019-N-1215. The docket will close on April 15, 2019. Submit either electronic or written comments by that date. Please note that late, untimely comments will not be considered. Electronic comments must be submitted on or before April 15, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 15, 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.

You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions

for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to make 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-1215 for “Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 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:** Amy Odegaard, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5151, Silver Spring, MD 20993, 301-796-8627, [amy.odegaard@fda.hhs.gov](mailto:amy.odegaard@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation’s food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA has established a public docket, Docket No. FDA-2019-N-1215, to receive input on post-marketing pediatric-focused safety reviews of products posted between October 12, 2018, and April 1, 2019, available on FDA’s website at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm> but not presented at the April 8, 2019, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108-155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA-2019-N-1215. The docket will open on April 2, 2019, and remain open until April 15, 2019. The post-marketing pediatric-focused safety reviews are for the following products from the following centers at FDA:

**Center for Biologics Evaluation and Research**

1. ADYNOVATE (Antihemophilic Factor [recombinant])
2. IXINITY (Coagulation Factor IX [Recombinant])
3. EPICEL (cultured epidermal autografts) (Humanitarian Device Exemption [HDE])

**Center for Drug Evaluation and Research**

1. ACZONE GEL (dapsone)
2. AIRDUO RESPICLICK (fluticasone propionate and salmeterol) and ARMONAIR RESPICLICK (fluticasone propionate)
3. AVELOX (moxifloxacin hydrochloride)

4. CALDOLOR INJECTION (ibuprofen)
5. CUBICAN INJECTION (daptomycin)
6. DEXILANT (dexlansoprazole)
7. EUCRISA OINTMENT (crisaborole)
8. LILETTA (levonorgestrel-releasing intrauterine system)
9. LYRICA (pregabalin)
10. NARCAN NASAL SPRAY (naloxone hydrochloride)
11. OFIRMEV (acetaminophen)
12. SELZENTRY (maraviroc)
13. SPIRIVA RESPIMAT (tiotropium bromide)
14. SYMBICORT INHALATION AEROSOL (budesonide/formoterol fumarate dehydrate)
15. TARCEVA (erlotinib hydrochloride)
16. VELCADE (bortezomib)

**Center for Devices and Radiological Health**

1. FLOURISH™ PEDIATRIC ESOPHAGEAL ATRESIA DEVICE (HDE)
2. LIPOSORBER LA-15 SYSTEM (HDE)
3. MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)

Dated: March 28, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06385 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-0179]

**Training Program for Regulatory Project Managers; Information Available to Industry**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration’s (FDA or the Agency) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

**DATES:** Pharmaceutical companies may send proposed agendas to the Agency by June 3, 2019.

**FOR FURTHER INFORMATION CONTACT:** Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993-0002, 301-796-0578, [dan.brum@fda.hhs.gov](mailto:dan.brum@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

**II. The Site Tours Program**

In this program, over a 2- to 3-day period, small groups (five or less) of CDER regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

**III. Site Selection**

All travel expenses associated with the Site Tours Program will be the

responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms that want to learn more about this training opportunity or that are interested in offering a site tour should respond by sending a proposed agenda by email directly to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06327 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2018-P-3691]

**Determination That CHLOR-TRIMETON ALLERGY 12 HOUR (Chlorpheniramine Maleate) Extended Release Tablets, 8 Milligrams and 12 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 milligrams (mg) and 12 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-1054.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, are the subject of NDA 007638, held by Bayer HealthCare LLC (Bayer) and initially approved on August 15, 1950. CHLOR-TRIMETON ALLERGY 12 HOUR is indicated for temporary relief of the following symptoms due to hay fever or other upper respiratory allergies: sneezing; runny nose; itchy, watery eyes; itching of the nose or throat.

In the 2005 NDA 007638 Annual Report received on October 14, 2005, Bayer notified FDA that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In a letter dated February 8, 2018, Bayer notified FDA that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended

release tablets, 12 mg, were being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Avanthi, LLC, c/o KVK-TECH, INC., submitted a citizen petition dated September 27, 2018 (Docket No. FDA-2018-P-3691), under 21 CFR 10.30, requesting that the Agency determine whether CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 12 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, were withdrawn for reasons of safety or effectiveness.

We have carefully reviewed our files for records concerning the withdrawal of CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CHLOR-TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate), extended release tablets, 8 mg and 12 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling

for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06382 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-0218]

#### Pulmonary-Allergy Drugs Advisory Committee; Cancellation

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

**ACTION:** Notice.

**SUMMARY:** The meeting of the Pulmonary-Allergy Drugs Advisory Committee scheduled for March 27, 2019, has been cancelled. This meeting was announced in the **Federal Register** of January 31, 2019. This meeting has been cancelled due to new information regarding the application. The Agency intends to continue evaluating the application and, as needed, will announce future meeting dates in the **Federal Register**.

#### FOR FURTHER INFORMATION CONTACT:

Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [PADAC@fda.hhs.gov](mailto:PADAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting, which was announced in the **Federal Register** of January 31, 2019 (84 FR 748).

Dated: March 28, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019-06389 Filed 4-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Pain Management Best Practices Inter-Agency Task Force

**AGENCY:** Office of the Assistant Secretary for Health, Office of the

Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force). The meeting will be open to the public; public comment sessions will be held during the meeting.

**DATES:** The Task Force meeting will be held on Thursday, May 9, 2019 from 10:00 a.m. to 5:30 p.m. and Friday, May 10, 2019, from 9:00 a.m. to 12:00 p.m. Eastern Time (ET). The agenda will be posted on the Task Force website at <https://www.hhs.gov/ash/advisory-committees/pain/index.html>.

**ADDRESSES:** U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

#### FOR FURTHER INFORMATION CONTACT:

Alicia Richmond Scott, Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Room 736E, Washington, DC 20201. Phone: 240-453-2816. Email: [paintaskforce@hhs.gov](mailto:paintaskforce@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) requires the Secretary of Health and Human Services, in cooperation with the Secretaries of Defense and Veterans Affairs, to convene the Task Force no later than two years after the date of the enactment of CARA and develop a report to Congress with updates on best practices and recommendations on addressing gaps or inconsistencies for pain management, including chronic and acute pain. The Task Force is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

In accordance with CARA, the Task Force will review clinical guidelines and identify gaps and/or inconsistencies for best practices for pain management, including chronic and acute pain, developed or adopted by federal agencies; propose updates to best practices and recommendations for identified gaps or inconsistencies; provide a 90 day the public comment period on any proposed updates and

recommendations; and develop a strategy for disseminating such proposed updates and recommendations to relevant federal agencies and the general public.

The Task Force will convene its third public meeting, on May 9–10, to discuss updates to existing best practices and recommendations based on gaps and inconsistencies for pain management, including chronic and acute pain. The Task Force will receive presentations on implementation and dissemination efforts. The Task Force will deliberate and vote the final recommendations for updates to best practices and recommendations for chronic and acute pain management and prescribing pain medication based on the components outlined in Section 101 of the CARA statute. Information about the final meeting agenda will be posted prior to the meeting on the Task Force website: <https://www.hhs.gov/ash/advisorycommittees/pain/index.html>.

Members of the public are invited to participate in person or by webcast. To join the meeting, individuals must pre-register at the Task Force website at <https://www.hhs.gov/ash/advisorycommittees/pain/index.html>. Seating will be provided first to those who have pre-registered. Anyone who has not pre-registered will be accommodated on a first come, first served basis if additional seats are available 10 minutes before the meeting starts. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying the Office of the Assistant Secretary for Health via email at [paintaskforce@hhs.gov](mailto:paintaskforce@hhs.gov) by April 29, 2019. The subject line of the email should read, "Task Force Meeting Accommodations." Non-U.S. citizens who plan to attend in person are required to provide additional information and must notify the Task Force staff via email at [paintaskforce@hhs.gov](mailto:paintaskforce@hhs.gov) 10 business days before the meeting, April 29, 2019. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at <https://www.hhs.gov/ash/advisorycommittees/pain/index.html>.

Members of the public can provide oral comments at the Task Force meeting on May 9, 2019, at 11:00 a.m.–11:30 a.m. ET. Please indicate your willingness to provide oral comments on the registration form which can be found at <https://www.hhs.gov/ash/advisorycommittees/pain/index.html>. Individuals who pre-register will be given priority to provide oral public

comment within the order they are received. The public comment period will not be extended beyond the allotted time on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Please note that the public comment period may end before the time indicated, following the last call for comments. Individuals who are not able to provide oral comments are encouraged to submit their written comments. Written comments should not exceed one page in length. Individuals submitting written comments should submit their comments through the Federal eRulemaking Portal at <http://www.regulations.gov>, docket number HHS–OS–2019–0003.

Dated: March 15, 2019.

**Vanila M. Singh,**

Chief Medical Officer, Chair, Pain Management Task Force, Office of the Assistant Secretary for Health.

[FR Doc. 2019–06328 Filed 4–1–19; 8:45 am]

**BILLING CODE 4150–28–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Biodefense Science Board: Call for Nominees**

**AGENCY:** Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) seeks applications from qualified individuals for membership on the National Biodefense Science Board (NBSB) or (Board). Terms of five members expire December 31, 2019; therefore, the HHS Secretary (Secretary) will appoint five new voting members. Applicants to those positions may be nominated by a relevant organization or may nominate themselves based on their expertise within the following stakeholder groups: Industry, academia, health care consumer organizations, and organizations representing other appropriate stakeholders. Please visit the NBSB website at <https://www.phe.gov/nbsb> for all application submission information, additional information regarding the qualifications expected for applicants, and application instructions.

**DATES:** *Nomination Period:* The nomination period is from April 15,

2019, to June 15, 2019, at 11:59 p.m. (EST).

**FOR FURTHER INFORMATION CONTACT:** CDR Christopher Perdue, MD, MPH, Designated Federal Official, NBSB, ASPR, HHS, office: 202–401–5837, email address: [christopher.perdue@hhs.gov](mailto:christopher.perdue@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to section 319M of the Public Health Service Act, HHS has established the NBSB to provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to HHS regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the ASPR on other matters related to public health emergency preparedness and response.

*Description of Duties:* The Board advises the Secretary and/or ASPR on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents. At the request of the Secretary and/or ASPR, the Board reviews and considers information and findings received from the working groups established under 42 U.S.C. 247d–7f(b). At the request of the Secretary and/or ASPR, the Board provides recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities. The Secretary and/or ASPR may assign additional advisory duties concerning public health emergency preparedness and response at his/her discretion.

*Structure:* The Board consists of 13 voting members, including the chairperson; additionally, there may be non-voting ex officio members. Pursuant to 42 U.S.C. 247d–7f(a), the Secretary appoints members and the chairperson from among the nation's preeminent scientific, public health, and medical experts, as follows: (a) Such federal officials as the Secretary determines are necessary to support the functions of the Board; (b) four individuals from the pharmaceutical, biotechnology, and device industries; (c) four individuals representing academia; and, (d) five other members as appointed by the Secretary, one of whom is a practicing health care professional, one of whom is from an organization representing health care consumers, one of whom has pediatric subject matter expertise, and

one of whom is a state, tribal, territorial, or local public health official. The Secretary appoints members who are not full-time or permanent part-time federal employees as non-pay special government employees.

Dated: March 27, 2019.

**Robert P. Kadlec,**

*Assistant Secretary for Preparedness and Response.*

[FR Doc. 2019-06329 Filed 4-1-19; 8:45 am]

**BILLING CODE 4150-37-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Biodefense Summit: Implementing the National Biodefense Strategy: Notification of Public Meeting and Solicitation of Advice

**AGENCY:** Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The HHS Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS) is announcing a public meeting, Biodefense Summit: Implementing the National Biodefense Strategy (Strategy). Implementing the Strategy involves partners among multiple sectors, including medical; public, animal, and plant health; emergency response; scientific and technical; law enforcement; industrial; academic; diplomatic; defense and security; intelligence; and nonproliferation and counterproliferation stakeholders. This meeting is being held to introduce the Strategy to these groups and to solicit feedback from them. The meeting will be open to representatives from invited organizations and the public.

**DATES:** The meeting will be held on April 17, 2019, from 8:45 a.m. to 5:00 p.m.

**ADDRESSES:** National Academies of Sciences Building, 2101 Constitution Ave. NW, Washington, DC 20418.

**FOR FURTHER INFORMATION CONTACT:** CAPT Theresa Lawrence, Ph.D.; Director, Division of Policy, Office of Strategy, Policy, Planning, and Requirements, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary of the Department of Health and Human Services; Thomas P. O'Neill Jr. Federal Building; 200 C St SW, Washington, DC 20515; [Theresa.Lawrence@HHS.GOV](mailto:Theresa.Lawrence@HHS.GOV); 202-401-5879

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On April 17, 2019, ASPR will convene a meeting at the National Academies of Sciences Building, 2101 Constitution Ave. NW, Washington, DC 20418 from 8:45 a.m.–5:00 p.m. with non-federal stakeholders to discuss and solicit input on implementing the National Biodefense Strategy, pursuant to National Security Presidential Memorandum 14, signed September 18, 2018.

The meeting will focus on a set of questions on the meeting agenda, posted at <http://www.phe.gov/biodefense>, on which the U.S. Government would specifically like to solicit comment. These questions concern matters such as the identification of gaps and opportunities for improvement in biodefense.

The meeting will be conducted as a series of panels where participants will be asked to discuss particular topics of interest to the Government. Each panel will include ample time for in-depth discussion of the issues surrounding each topic.

The meeting is open to the public and free of charge. Pre-registration is encouraged, however, registration will be restricted due to limited space. Information about registering for the meeting is available at <http://www.phe.gov/biodefense>. Any groups or individuals who cannot attend the meeting are encouraged to submit written comments.

**Background:** Biological threats are among the most serious threats facing the United States. In today's interconnected world, biological incidents have the potential to cost thousands of American lives, cause significant anxiety, and disrupt travel and trade. The Strategy sets the course for the United States to combat the serious biothreats our country faces, whether they arise from natural outbreaks of disease, accidents involving high consequence pathogens, or the actions of terrorists or state actors. Preparing for biothreats is a critical aspect of our national security, and the Strategy encompasses five goals for strengthening the biodefense enterprise including:

1. Enabling risk awareness to inform decision-making across the biodefense enterprise;
2. Ensuring biodefense enterprise capabilities to prevent bioincidents;
3. Ensuring biodefense enterprise preparedness to reduce the impacts of bioincidents;
4. Rapidly responding to limit the impacts of bioincidents; and
5. Facilitating recovery to restore the community, the economy, and the environment after a bioincident.

The National Biodefense Strategy calls for engagement and cooperation across all levels of government, to include state, local, tribal, and territorial governments, as well as internationally. It involves partnership with multiple sectors, including the medical; public, animal, and plant health; emergency response; scientific and technical; law enforcement; industrial; academic; diplomatic; defense and security; intelligence; and nonproliferation and counterproliferation sectors, among others. Engagement with non-governmental organizations and the private sector is critical to prevent the spread of disease and respond to the next outbreak before it becomes an epidemic.

**Streaming Webcast of the Public Meeting:** This public meeting will also be webcast. Information about registering for the webcast will be available at <http://www.phe.gov/biodefense>.

**Meeting Summary:** Please be advised that a summary of the meeting will be accessible at <http://www.phe.gov/biodefense> as soon as it is available.

**Written Public Input is Encouraged:** Even though space or time constraints may preclude some interested members of the public from attending, we understand that these issues are broadly of interest to the American people. Given the importance of the Nation's biodefense to every American, the public is encouraged to submit written comments on a set of questions on the meeting agenda posted at [www.phe.gov/biodefense](http://www.phe.gov/biodefense), on which the U.S. Government would specifically like to solicit comment. These questions concern such matters as the identification of gaps and opportunities for improvement in biodefense. Comments should be submitted to [ASPRBIO@hhs.gov](mailto:ASPRBIO@hhs.gov) or the address above by May 1, 2019.

Dated: March 27, 2019.

**Robert P. Kadlec,**

*Assistant Secretary for Preparedness and Response.*

[FR Doc. 2019-06330 Filed 4-1-19; 8:45 am]

**BILLING CODE 4150-37-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Substance Abuse and Mental Health Services Administration****Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at <http://www.samhsa.gov/workplace>.

**FOR FURTHER INFORMATION CONTACT:**

Charles LoDico, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N02C, Rockville, Maryland 20857; 240-276-2600 (voice).

**SUPPLEMENTARY INFORMATION:** The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines were initially developed in accordance with

Executive Order 12564 and section 503 of Public Law 100-71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

**HHS-Certified Instrumented Initial Testing Facilities**

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780-784-1190, (Formerly: Gamma-Dynacare Medical Laboratories)

**HHS-Certified Laboratories**

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 844-486-9226  
 Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)  
 Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804-378-9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)  
 Baptist Medical Center-Toxicology Laboratory, 11401 I-30, Little Rock, AR 72209-7056, 501-202-2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)  
 Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917  
 Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800-442-0438, (Formerly: STERLING Reference Laboratories)

Desert Tox, LLC, 10221 North 32nd Street, Suite J, Phoenix, AZ 85028, 602-457-5411  
 DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800-235-4890  
 Dynacare\*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630, (Formerly: Gamma-Dynacare Medical Laboratories)  
 ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609  
 Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387  
 Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986, (Formerly: Roche Biomedical Laboratories, Inc.)  
 Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)  
 Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)  
 LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)  
 MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244  
 Legacy Laboratory Services—MetroLab, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295  
 Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088, Testing for Veterans Affairs (VA) Employees Only  
 Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)  
 Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888-635-5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800-729-6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800-255-2159

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755-5235, 301-677-7085, Testing for Department of Defense (DoD) Employees Only

\* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

**Charles P. LoDico,**  
*Chemist.*

[FR Doc. 2019-06326 Filed 4-1-19; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2019-0042]

#### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0033

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0033, Display of Fire Control Plans for Vessels; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before June 3, 2019.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2019-0042] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public participation and request for comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG-612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR AVE. SE, STOP 7710, WASHINGTON, DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

#### **SUPPLEMENTARY INFORMATION:**

#### **Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains

information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2019-0042], and must be received by June 3, 2019.

#### **Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have

provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

### Information Collection Request

*Title:* Display of Fire Control Plans for Vessels.

*OMB Control Number:* 1625-0033.

*Summary:* This information collection is for the posting or display of specific plans on certain categories of commercial vessels. The availability of these plans aid firefighters and damage control efforts in response to emergencies.

*Need:* Under 46 U.S.C. 3305 and 3306, the Coast Guard is responsible for ensuring the safety of inspected vessels and has promulgated regulations in 46 CFR parts 35, 78, 97, 109, 131, 169, and 196 to ensure that safety standards are met.

*Forms:* None.

*Respondents:* Owners and operators of vessels.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has decreased from 576 hours to 472 hours a year due to a decrease in the estimated number of respondents.

*Authority:* The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: March 21, 2019.

**James D. Roppel,**

*Chief, U.S. Coast Guard, Office of Information Management.*

[FR Doc. 2019-06324 Filed 4-1-19; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2006-23846-0042]

### Consolidated Cruise Ship Security Regulations

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Coast Guard announces the availability of an updated Prohibited Items List (PIL) for Cruise Vessels. On March 19, 2018, the Coast Guard published the Consolidated Cruise Ship Security Regulations Final Rule (FR) and issued a PIL of dangerous substances and devices. The Coast Guard referenced ammunition in the Notice of Proposed Rulemaking (NPRM) published on December 10, 2014, and the Final Rule, but inadvertently omitted ammunition from the separate

PIL document that was included in the docket. The updated PIL is posted on the U.S. Coast Guard Homeport website.

**FOR FURTHER INFORMATION CONTACT:** For information about this document call or email the Cargo and Facilities Division (CG-FAC-2), 202-372-1092, *cgfac@uscg.mil*.

**SUPPLEMENTARY INFORMATION:** In connection with the Consolidated Cruise Ship Security Regulations Final Rule (83 FR 12086), the Coast Guard developed a PIL that was similar, but not identical to, one that is used by the Transportation Security Administration (TSA) at airports, which defines certain items that cannot not be brought on board a cruise ship by passengers on their persons or in checked luggage. In the NPRM (79 FR 73255), the Coast Guard explained that prohibiting the items listed on the PIL was not intended to be a new requirement, but rather an interpretation of the existing requirement, which is located in 33 CFR 104.295(a) and 105.290(a), that cruise ship and cruise ship terminal operators “[s]creen all persons, baggage, and personal effects for dangerous substances and devices.” Considering that the definition of “dangerous substances and devices” in 33 CFR 101.105 means “any material, substance, or item that reasonably has the potential to cause a transportation security incident [TSI]”, the Coast Guard published the PIL as an interpretive document indicating which items the Coast Guard believes are “dangerous substances and devices” at all times, while other items may or may not be considered such at the Facility Security Officer’s discretion. The Coast Guard notes that cruise ship operators are free to prohibit additional items on their vessels if they believe they are dangerous, or for any other reason, and also notes that most cruise lines already advertise lists of prohibited items that are extremely similar to, if not more extensive than, the published PIL.

The presence of ammunition in secured areas of cruise ship terminals and unsecured areas on cruise vessels represents a significant threat to cruise ship passengers and the maritime transportation personnel who service them. The Coast Guard decided to published an updated list, including ammunition, due to an increase in the number of reports of bulk quantities of ammunition (>100 rounds) detected by screeners at cruise terminals as well as reports of ammunition successfully eluding security countermeasures and being identified aboard cruise vessels.

The publication of an updated PIL details those items that are prohibited

from secured areas in cruise terminals and unsecured areas on cruise vessels and ensures a safer environment by prohibiting dangerous items across the entire industry.

This notice is issued under authority of 5 U.S.C. 552(a).

Dated: March 27, 2019.

**Jennifer F. Williams,**

*Captain, U.S. Coast Guard, Director of Inspections and Compliance.*

[FR Doc. 2019-06310 Filed 4-1-19; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

### Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds on Customs Duties

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** This notice advises the public that the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties will remain the same as the previous quarter. For the calendar quarter beginning April 1, 2019, the interest rates for overpayments will be 5 percent for corporations and 6 percent for non-corporations, and the interest rate for underpayments will be 6 percent for both corporations and non-corporations. This notice is published for the convenience of the importing public and U.S. Customs and Border Protection personnel.

**DATES:** The rates announced in this notice are applicable as of April 1, 2019.

**FOR FURTHER INFORMATION CONTACT:** Bruce Ingalls, Revenue Division, Collection Refunds & Analysis Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 298-1107.

### SUPPLEMENTARY INFORMATION:

#### Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85-93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 provides different interest rates

applicable to overpayments: One for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2019-05, the IRS determined the rates of interest for the calendar quarter beginning April 1, 2019, and ending on June 30, 2019. The

interest rate paid to the Treasury for underpayments will be the Federal short-term rate (3%) plus three percentage points (3%) for a total of six percent (6%) for both corporations and non-corporations. For corporate overpayments, the rate is the Federal short-term rate (3%) plus two percentage points (2%) for a total of five percent (5%). For overpayments made by non-corporations, the rate is the Federal short-term rate (3%) plus three percentage points (3%) for a total of six percent (6%). These interest rates used to calculate interest on overdue

accounts (underpayments) and refunds (overpayments) of customs duties remain the same as the previous quarter. These interest rates are subject to change for the calendar quarter beginning July 1, 2019, and ending on September 30, 2019.

For the convenience of the importing public and U.S. Customs and Border Protection personnel the following list of IRS interest rates used, covering the period from July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpayments (Eff. 1-1-99) (percent)
070174	063075	6	6	
070175	013176	9	9	
020176	013178	7	7	
020178	013180	6	6	
020180	013182	12	12	
020182	123182	20	20	
010183	063083	16	16	
070183	123184	11	11	
010185	063085	13	13	
070185	123185	11	11	
010186	063086	10	10	
070186	123186	9	9	
010187	093087	9	8	
100187	123187	10	9	
010188	033188	11	10	
040188	093088	10	9	
100188	033189	11	10	
040189	093089	12	11	
100189	033191	11	10	
040191	123191	10	9	
010192	033192	9	8	
040192	093092	8	7	
100192	063094	7	6	
070194	093094	8	7	
100194	033195	9	8	
040195	063095	10	9	
070195	033196	9	8	
040196	063096	8	7	
070196	033198	9	8	
040198	123198	8	7	
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	123110	4	4	3
010111	033111	3	3	2
040111	093011	4	4	3
100111	033116	3	3	2
040116	033118	4	4	3

Beginning date	Ending date	Under-payments (percent)	Over-payments (percent)	Corporate overpayments (Eff. 1-1-99) (percent)
040118 .....	123118	5	5	4
010119 .....	063019	6	6	5

Dated: March 27, 2019.

**Samuel D. Grable,**

*Assistant Commissioner and Chief Financial Officer, Office of Finance.*

[FR Doc. 2019-06292 Filed 4-1-19; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[LLCON00000-L18200000.XX0000-19X]

#### Notice of Public Meeting, Northwest Resource Advisory Council

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Northwest Resource Advisory Council (RAC) will meet as indicated below.

**DATES:** The meeting will be held on April 25, 2019, from 8:00 a.m. to 3:00 p.m.

**ADDRESSES:** The meeting will be held at the Rio Blanco County Fairgrounds 4H Community Center, 700 Sulphur Creek Road in Meeker, Colorado.

**FOR FURTHER INFORMATION CONTACT:** David Boyd, Public Affairs Specialist, Northwest District Office, 2300 River Frontage Road, Silt, Colorado 81652. Phone: (970) 876-9008. Email: [dboyd@blm.gov](mailto:dboyd@blm.gov). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The 15-member Northwest Colorado RAC advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of public land issues in the Northwest District including the Colorado River Valley, Kremmling, Little Snake and White

River field offices. Agenda items for this meeting include wild horse management, an informational presentation about a campground fee proposal, the Canyon Pintado National Historic District, travel management, and district and field manager updates. This meeting is open to the public, and public comment periods will be held at 10 a.m. and 2 p.m. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. The public may present written comments to the Northwest RAC. 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.

Summary minutes for the RAC meeting will be maintained in the Northwest District Office and will be available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting. Previous RAC meeting minutes and agendas are available at: <https://go.usa.gov/xEnzP>.

**Jamie E. Connell,**

*BLM Colorado State Director.*

[FR Doc. 2019-06378 Filed 4-1-19; 8:45 am]

**BILLING CODE 4310-JB-P**

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Luxury Vinyl Tile and Components Thereof, DN 3376*; the Commission is soliciting comments on any public interest issues raised by the

complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

**FOR FURTHER INFORMATION CONTACT:** Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>, and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Mohawk Industries, Inc., Flooring Industries Ltd. Sarl, and IVC US Inc. on March 25, 2019. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain bone cements, components thereof and products containing the same. The complaint names as respondents: ABK Trading Corp. of Katy, TX; Anhui Hanhua Building Materials Co., Ltd. of China; Aspecta North America, LLC of Norwalk, CT; Aurora Flooring LLC of Kennesaw, GA; Benchwick Construction Products Ltd. of China; Changzhou Jinuo Decorative Material Co., Ltd. of China; Changzhou Marco Merit International Solutions Co. of China; Changzhou Runchang Wood Co., Ltd. of China; Christina & Son Inc.

of Temple City, CA; Chungstine Inc. d/b/a Expert Hardwood Flooring of Ontario, CA; Davati Group LLC of Austin, TX; DeSoto Sales, Inc. of Canoga Park, CA; Global Wood Inc. of Walnut, CA; Go-Higher Trading (Jiangsu) Co., Ltd. of China; Golden Tree Import & Export Inc. of Temple City, CA; Halstead New England Corp of Norwalk, CT; Hangzhou Kingdom Import & Export Trading Co. Ltd. of China; IN.id Corp. of Diamond Bar, CA; JC Int'l Trading, Inc. of City of Industry, CA; Jiangsu Divine Building Technology Development Co. Ltd. of China; Jiangsu Lejia Plastic Co. Ltd. of China; Jiangsu Licheer Wood Co., Ltd. of China; Jiangsu TongSheng Decorative Materials Co., Ltd. of China; Jkgy Inc. d/b/a Nextar Trading of City of Industry, CA; KJ Carpet Wholesale, Inc. of Pomona, CA; Maxwell Flooring Distribution LLC of Houston, TX; Metroflor Corp. of Norwalk, CT; Mountain High Corp. of El Monte, CA; Mr. Hardwood Inc. of Acworth, GA; National Coverings, LLC of Ft. Lauderdale, FL; Nextar Wholesale of City of Industry, CA; Northann Distribution Center Inc. of Sacramento, CA; Pentamax Inc. of Compton, CA; RBT Industries LLC d/b/a Hardwood Bargains of Austin, TX; RC Vinyl Inc. of City of Industry, CA; Royal Family Inc. of Temple City, CA; Sam Houston Hardwood Inc. of Houston, TX; Zhejiang Changxing Senda Bamboo and Wood Products Co. Ltd. of China; Zhangjiagang Elegant Home-Tech Co. Ltd. of China; Zhangjiagang Elegant Plastics Co. Ltd. of China; Zhangjiagang Yihua Plastics Co., Ltd. of China; Zhangjiagang Yihua Rundong New Material Co. Ltd. of China; Zhejiang Kimay Building Material Technology Co., Ltd. of China; Zhejiang Kingdom Flooring Plastic Co., Ltd. of China; and Zhejiang Walrus New Material Co., Ltd. of China. The complainant requests that the Commission issue a general exclusion order, cease and desist orders, and a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or

directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues should be filed no later than by close of business nine calendar days after the date of publication of this notice in the **Federal Register**. Complainant may file a reply to any written submission no later than the date on which complainant's reply would be due under § 210.8(c)(2) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(c)(2)).

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3376") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures<sup>1</sup>). Persons with

<sup>1</sup> Handbook for Electronic Filing Procedures: [https://www.usitc.gov/documents/handbook\\_on\\_filing\\_procedures.pdf](https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf).

questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,<sup>2</sup> solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.<sup>3</sup>

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: March 27, 2019.

**Katherine Hiner,**

*Acting Secretary to the Commission.*

[FR Doc. 2019–06377 Filed 4–1–19; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1139]

### Certain Electronic Nicotine Delivery Systems and Components Thereof; Notice of Commission Decision Not To Review an Initial Determination Granting-in-Part a Joint Motion To Amend the Complaint and Notice of Investigation

**AGENCY:** U.S. International Trade Commission.

<sup>2</sup> All contract personnel will sign appropriate nondisclosure agreements.

<sup>3</sup> Electronic Document Information System (EDIS): <https://edis.usitc.gov>.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (“ID”) (Order No. 10) of the Administrative Law Judge (“ALJ”) granting-in-part a joint motion to amend the complaint and notice of investigation (“NOI”).

**FOR FURTHER INFORMATION CONTACT:** Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** On December 13, 2018, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“section 337”), based on a complaint filed by Juul Labs, Inc. of San Francisco, California (“Complainant”). See 83 FR 64156–57 (Dec. 13, 2018). The complaint, as amended and supplemented, alleges a violation of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic nicotine delivery systems and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,070,669; U.S. Patent No. 10,076,139; U.S. Patent No. 10,045,568; U.S. Patent No. 10,058,130; and U.S. Patent No. 10,104,915. See *id.* The NOI names numerous respondents, including: Limitless Mod Co. of Simi Valley, California (“Limitless”); Asher Dynamics, Inc. of Chino, California (“Asher Dynamics”); and Ply Rock of Chino, California. See *id.* The Office of Unfair Import Investigations (“OUII”) is also a party to the investigation. See *id.*

On February 1, 2019, Complainant and respondents Limitless, Asher Dynamics, and Ply Rock (collectively, “the Asher Respondents”) filed a joint

motion to amend the complaint and NOI to: (1) Correct the name of respondent Limitless to “Limitless MOD, LLC” and (2) terminate the investigation as to the Asher Respondents. On February 13, 2019, OUII filed a response in support of the joint motion.

On February 28, 2019, the ALJ issued the subject ID (Order No. 10) granting-in-part the joint motion. The ID finds that, under Commission Rule 210.14(b), 19 CFR 210.14(b), “good cause exists to amend the complaint and notice of investigation to conform to the correct information.” See ID at 2. In addition, the ID finds that “this amendment would not prejudice the public interest or the rights of the parties to the investigation.” See *id.* The ID further notes that “[t]he request for termination of the Asher Respondents will be ruled upon in a separate order.” See *id.* at 2 n.2; Order No. 11 (Feb. 28, 2019).

No petition for review of the subject ID was filed. The Commission has determined not to review the ID.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission’s Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: March 27, 2019.

**Katherine Hiner,**

*Acting Secretary to the Commission.*

[FR Doc. 2019–06321 Filed 4–1–19; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0073]

#### Agency Information Collection Activities; Proposed eCollection eComments Requested; Furnishing of Samples

**AGENCY:** Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

**ACTION:** 30-Day notice.

**SUMMARY:** The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** The proposed information collection was previously published in the **Federal Register**, on February 5,

2019, allowing for a 60-day comment period. Comments are encouraged and will be accepted for an additional 30 days until May 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact: Anita Scheddel, Program Analyst, Explosives Industry Programs Branch, either by mail 99 New York Ave NE, Washington, DC 20226, or by email at [eipb-informationcollection@atf.gov](mailto:eipb-informationcollection@atf.gov) or by telephone at 202–648–7158. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to [OIRA\\_submissions@omb.eop.gov](mailto:OIRA_submissions@omb.eop.gov).

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *The Title of the Form/Collection:* Furnishing of Samples.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: None.

*Component:* Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* Business or other for-profit.

*Other:* None.

*Abstract:* Pursuant to 18 U.S.C. Chapter 40 § 843 (i) (1), ATF requires licensed manufacturers and importers and persons who manufacture or import explosives materials or ammonium nitrate to submit samples at the request of the Director. This collection of information is contained in 27 CFR 555.110.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 100 respondents will utilize this information collection, and it will take each respondent approximately 30 minutes to provide their response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 50 hours, which is equal to 100 (# of respondents) \* 1 (# of responses per respondents) \* .5 (30 minutes).

(7) *An Explanation of the Change in Estimates:* The adjustments associated with this collection from the previous renewal include a reduction in the total respondents and burden hours by 2,250 and 1,125 hours respectively, since the previous renewal in 2016.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: March 27, 2019.

**Melody Braswell,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2019-06297 Filed 4-1-19; 8:45 am]

**BILLING CODE 4410-14-P**

## DEPARTMENT OF JUSTICE

### Federal Bureau of Investigation

#### Meeting of the Compact Council for the National Crime Prevention and Privacy Compact

**AGENCY:** Federal Bureau of Investigation, Department of Justice.

**ACTION:** Meeting notice.

**SUMMARY:** The purpose of this notice is to announce a meeting of the National

Crime Prevention and Privacy Compact Council (Council) created by the National Crime Prevention and Privacy Compact Act of 1998 (Compact).

**DATES:** The Council will meet in open session from 9 a.m. until 5 p.m., on May 15, 2019.

**ADDRESSES:** The meeting will take place at the Hyatt Regency Columbus, 350 North High Street, Columbus, Ohio, 614-280-3004.

**FOR FURTHER INFORMATION CONTACT:** Inquiries may be addressed to Mrs. Chasity S. Anderson, FBI Compact Officer, Module D3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, telephone 304-625-2803, facsimile 304-625-2868.

**SUPPLEMENTARY INFORMATION:** Thus far, the Federal Government and 31 states are parties to the Compact which governs the exchange of criminal history records for licensing, employment, and similar purposes. The Compact also provides a legal framework for the establishment of a cooperative federal-state system to exchange such records.

The United States Attorney General appointed 15 persons from state and federal agencies to serve on the Council. The Council will prescribe system rules and procedures for the effective and proper operation of the Interstate Identification Index system for noncriminal justice purposes.

Matters for discussion are expected to include:

- (1) Consideration to Address Illegible Prints
- (2) Summary of the National Fingerprint File Participation Implementation Plans

The meeting will be open to the public on a first-come, first-seated basis. Any member of the public wishing to file a written statement with the Council or wishing to address this session of the Council should notify the Federal Bureau of Investigation (FBI) Compact Officer, Mrs. Chasity S. Anderson at 304-625-2803, at least 24 hours prior to the start of the session. The notification should contain the individual's name and corporate designation, consumer affiliation, or government designation, along with a short statement describing the topic to be addressed and the time needed for the presentation. Individuals will ordinarily be allowed up to 15 minutes to present a topic.

Dated: March 26, 2019.

**Chasity S. Anderson,**

*FBI Compact Officer, Criminal Justice Information Services Division, Federal Bureau of Investigation.*

[FR Doc. 2019-06357 Filed 4-1-19; 8:45 am]

**BILLING CODE 4410-02-P**

## NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

### Institute of Museum and Library Services

#### Notice of Proposed Information Collection Request: Evaluation of the Museums for Digital Learning (MDL) Project

**AGENCY:** Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

**ACTION:** Notice, request for comments on this collection of information.

**SUMMARY:** The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act. This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. This action is to create the overall evaluation plan, survey and data collection instruments and instructions for the various evaluation techniques to be used at different points in the development and implementation of the MDL pilot initiative for the next two years.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

**DATES:** Written comments must be submitted to the office listed in the addressee section below on or before June 1, 2019.

IMLS is particularly interested in comments that help the agency to:

- 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 submissions of responses.

**ADDRESSES:** Send comments to: Dr. Sandra Webb, Director, Office of Grants Policy and Management, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Dr. Webb can be reached by Telephone: 202–653–4718 Fax: 202–653–4608, or by email at [swebb@imls.gov](mailto:swebb@imls.gov), or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

**FOR FURTHER INFORMATION CONTACT:** Helen Wechsler, Supervisory Grants Management Specialist, Office of Museum Services, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. She can be reached by Telephone: 202–653–4717 Fax: 202–653–4608, or by email at [hwechsler@imls.gov](mailto:hwechsler@imls.gov), or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. Our vision is a nation where museums and libraries work together to transform the lives of individuals and communities. To learn more, visit [www.imls.gov](http://www.imls.gov).

**II. Current Actions**

The *Museums for Digital Learning* (MDL) is a project funded by IMLS that seeks to identify and test new ways that digitized museum collections can be made available in the form of engaging digital educational resources via a pilot digital platform to educators around the country seeking to engage their students with all subjects. This two-year project is being led by the Indianapolis Museum of Art at Newfields in collaboration with two museum content partners—The Field Museum and History Colorado and a team of K–12 educators. Once the pilot suite of online products has been created by the project team, they will be tested in the classrooms of the ten educational partners. Testing and validation of the content contribution approach and standard templates to the pilot platform will be conducted with a cohort of up

to ten additional museums of various sizes and disciplines.

This project aligns with IMLS's strategic goal and priorities of building the digital capacity of the sector. MDL will catalyze and empower museums to come together and create a national model with a shared vision to thoughtfully assess some of the critical gaps in the current platforms and digital access/use models, and then leverage the power of a shared digital platform to provide easy-to-access, interdisciplinary, and dynamic content from museums in digital format for educators and students.

The project will benefit the national education sector by providing a model for museums to collaborate as a sector with educators and engaging them not just as users of museum content and services, but as co-creators and co-facilitators of student learning; a suite of curriculum enhancing and student-centric digital collections-based educational resources; and an opportunity to pilot-test and improve the resources from the formative evaluation to better meet the needs of the nation's learners.

A product and process evaluation of the MDL project will be completed by a third party evaluator with experience in evaluating digital education platforms produced by the cultural heritage community. The process evaluation aspect will assess the overall planning and implementation of the collaborative model of MDL between the partner museums and the educators, as well as the effectiveness of the training and ease of content contribution of the ten additional museums. Much of the front-end and user experience design of the MDL platform will be formed through the collaboration and co-creation process between the cooperator, lead museum content partners, and the team of educators. The product evaluation will assess the ease of access and educational value of the collections-based digital education products for educators and students.

This action is to create the overall evaluation plan, survey and data collection instruments and instructions for the various evaluation techniques to be used at different points in the development and implementation of the MDL pilot initiative for the next two years.

*Agency:* Institute of Museum and Library Services.

*Title:* Museums for Digital Learning Evaluation.

*OMB Number:* 3137–TBD.

*Frequency:* Once.

*Affected Public:* Museum staff, teachers.

*Number of Respondents:* TBD.

*Estimated Average Burden per Response:* TBD hours.

*Estimated Total Annual Burden:* TBD hours.

*Total Annualized capital/startup costs:* N/A.

*Total Annual costs:* TBD.

*Public Comments Invited:* Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

Dated: March 28, 2019.

**Kim Miller,**

*Grants Management Specialist, Institute of Museum and Library Services.*

[FR Doc. 2019–06361 Filed 4–1–19; 8:45 am]

**BILLING CODE 7036–01–P**

**NATIONAL SCIENCE FOUNDATION**

**Proposal Review Panel for Materials Research; Notice of Meeting**

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

*Name and Committee Code:* Proposal Review Panel for Materials Research—STC Center for Integrated Quantum Materials (CIQM), Massachusetts Institute of Technology (#1203) Site Visit.

*Date and Time:* May 7, 2019, 6:30 p.m. to 9:00 p.m., May 8, 2019, 7:20 a.m. to 7:00 p.m., May 9, 2019; 7:30 a.m. to 3:30 p.m.

*Place:* Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, MA 02138.

*Type of Meeting:* Part-open.

*Contact Person:* Dr. Tomasz Durakiewicz, Program Director, Condensed Matter Physics (CMP), Division of Materials Research, Room E 9344, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone (703) 292–4892.

*Purpose of Meeting:* NSF site visit to provide advice and recommendations concerning further NSF support for the Center.

**Agenda**

*May 7, 2019*

6:30 p.m.–9:00 p.m. Review Panel members meeting and orientation (Closed)

*May 8, 2019*

7:20 a.m.–8:00 a.m. Light Breakfast with NSF Review Panel

8:00 a.m.–8:50 a.m. Directors Overview—Bob Westervelt, Naomi Brave (Closed)

8:50 a.m.–9:00 a.m. Discussion (Closed)  
 9:00 a.m.–9:35 a.m. Research Area 1:  
 Novel vdW Heterostructures—  
 Philip Kim  
 9:35 a.m.–9:45 a.m. Discussion  
 9:45 a.m.–10:20 a.m. Research Area 2:  
 Discovery of New TI Crystals—  
 Joseph Checkelsky  
 10:20 a.m.–10:30 a.m. Discussion  
 10:30 a.m.–10:45 a.m. Break  
 10:45 a.m.–11:20 a.m. Research Area 3:  
 Topologically Protected Qubits—  
 Amir Yacoby  
 11:20 a.m.–11:30 a.m. Discussion  
 11:30 a.m.–12:05 p.m. Research Area 4:  
 Quantum Networks—Marko Loncar  
 12:05 p.m.–12:15 p.m. Discussion  
 12:15 p.m.–12:40 p.m. Executive  
 Session for Site Visit Team and NSF  
 (Closed)  
 12:40 p.m.–1:40 p.m. Lunch—Site Visit  
 Team with Students and Postdocs  
 (Closed)  
 1:40 p.m.–2:10 p.m. Education &  
 Outreach, and the CIQM Education  
 Supplement: Tina Brower-Thomas  
 2:10 p.m.–2:20 p.m. Diversity Plan:  
 Steven Richardson  
 2:20 p.m.–2:30 p.m. Discussion  
 2:30 p.m.–2:50 p.m. Science  
 Communication, and the Quantum  
 Matters Competition Supplement:  
 Carol Lynn Alpert  
 2:50 p.m.–3:00 p.m. Discussion  
 3:00 p.m.–3:20 p.m. ALS Clear  
 Supplement: Jeanne Reis, Mandy  
 Houghton  
 3:20 p.m.–3:30 p.m. Discussion  
 3:30 p.m.–3:50 p.m. Knowledge  
 Transfer, Industrial and Other  
 Collaborations—Tomas Palacios  
 3:50 p.m.–4:00 p.m. Discussion  
 4:00 p.m.–5:00 p.m. Poster Session  
 5:00 p.m.–6:30 p.m. Executive Session  
 Site Visit Team and NSF: Prepare  
 Questions (Closed)  
 6:30 p.m.–6:45 p.m. Site Visit Team  
 Meets with Director and Executive  
 Committee (Closed)  
 7:00 p.m. Working Dinner for All CIQM  
 Faculty & Staff

*May 9, 2019*

7:30 a.m.–8:00 a.m. Light Breakfast  
 8:00 a.m.–10:00 a.m. Executive  
 Session—Director's Response  
 (CIQM Executive Committee)  
 (Closed)  
 10:00 a.m.–10:10 a.m. Break  
 10:10 a.m.–11:00 a.m. Executive Session  
 of Site Visit Team (Closed)  
 11:00 a.m.–12:00 p.m. Meeting with  
 Administrators Only (no PIs)/  
 Institutional Support (Closed)  
 12:00 p.m.–3:00 p.m. Site Review Team  
 prepares Site Visit Report—  
 Working lunch (Closed)  
 3:00 p.m.–3:30 p.m. Debriefing with  
 STC Director and Executive  
 Committee (Closed)

Dated: March 27, 2019.

**Crystal Robinson,**

*Committee Management Officer.*

[FR Doc. 2019–06301 Filed 4–1–19; 8:45 am]

**BILLING CODE 7555–01–P**

## NUCLEAR REGULATORY COMMISSION

[NRC–2019–0072]

### Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

**AGENCY:** Nuclear Regulatory  
Commission.

**ACTION:** License amendment request  
(LAR); notice of opportunity to  
comment, request a hearing, and  
petition for leave to intervene; order  
imposing procedures.

**SUMMARY:** The U.S. Nuclear Regulatory  
Commission (NRC) received and is  
considering approval of one amendment  
request. The amendment request is for  
Oconee Nuclear Station, Units 1, 2, and  
3. For the amendment request, the NRC  
proposes to determine that it involves  
no significant hazards consideration.  
Because the amendment request  
contains sensitive unclassified non-  
safeguards information (SUNSI) an  
order imposes procedures to obtain  
access to SUNSI for contention  
preparation.

**DATES:** Comments must be filed by May  
2, 2019. A request for a hearing must be  
filed by June 3, 2019. Any potential  
party as defined in § 2.4 of title 10 of the  
*Code of Federal Regulations* (10 CFR)  
who believes access to SUNSI is  
necessary to respond to this notice must  
request document access by April 12,  
2019.

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

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2019–0072. Address questions about NRC Docket IDs in *Regulations.gov* to Krupskaya Castellon; telephone: 301–287–9221; email: [Krupskaya.Castellon@nrc.gov](mailto:Krupskaya.Castellon@nrc.gov). For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–

A60M, U.S. Nuclear Regulatory  
Commission, Washington, DC 20555–  
0001, ATTN: Program Management,  
Announcements and Editing Staff.

For additional direction on obtaining  
information and submitting comments,  
see “Obtaining Information and  
Submitting Comments” in the  
**SUPPLEMENTARY INFORMATION** section of  
this document.

#### FOR FURTHER INFORMATION CONTACT:

Lynn Ronewicz, Office of Nuclear  
Reactor Regulation, U.S. Nuclear  
Regulatory Commission, Washington DC  
20555–0001; telephone: 301–415–1927;  
email: [Lynn.Ronewicz@nrc.gov](mailto:Lynn.Ronewicz@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Obtaining Information and Submitting Comments

###### A. Obtaining Information

Please refer to Docket ID NRC–2019–  
0072, facility name, unit number(s),  
plant docket number, application date,  
and subject when contacting the NRC  
about the availability of information for  
this action. You may obtain publicly-  
available information related to this  
action by any of the following methods:

- *Federal Rulemaking Website:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2019–0072.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

###### B. Submitting Comments

Please include Docket ID NRC–2019–  
0072 facility name, unit number(s),  
plant docket number, application date,  
and subject in your comment  
submission.

The NRC cautions you not to include  
identifying or contact information that  
you do not want to be publicly  
disclosed in your comment submission.  
The NRC will post all comment  
submissions at <http://www.regulations.gov> as well as enter the

comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notice of amendments containing SUNSI.

## III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for the amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

### A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or

order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the

Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

#### *B. Electronic Submissions (E-Filing)*

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the

proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at [hearing.docket@nrc.gov](mailto: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-submittals.html>, by email to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

*Duke Energy Carolinas, LLC, Docket Nos. 50-269, 50-270, and 50-287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina*

*Date of amendment request:* September 14, 2018, as supplemented by letter dated January 24, 2019. Publicly-available versions are in ADAMS under Accession Nos. ML18264A018 and ML19036A625, respectively.

*Description of amendment request:* This amendment request contains SUNSI. The amendments would revise the Updated Final Safety Analysis Report (UFSAR) regarding the tornado LB [licensing basis] by: Crediting the Standby Shutdown Facility as the assured mitigation path following a tornado, with the assumed initial conditions of loss of all alternating current power to all units with significant damage to one unit, incorporating the use of tornado missile probabilistic methodology (TORMIS), and eliminating the spent fuel pool (SFP) to high pressure injection (HPI) flow path for reactor coolant makeup. This amendment request supersedes the request dated June 26, 2008 (ADAMS Accession No. ML081840371), and its associated tornado documentation with exceptions, as discussed in the licensee's letter dated January 24, 2019. The request dated June 26, 2008, was

noticed in the **Federal Register** on September 23, 2008 (73 FR 54865).

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, with NRC staff edits in square brackets:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

*Justification:* Although a tornado does not constitute a previously-evaluated UFSAR Chapter 15 design basis accident or transient as described in 10 CFR 50.36(c)(2), it is a design basis criterion that is required to be considered in design of structure, systems, or components. The possibility of a tornado striking Oconee Nuclear Station [ONS] is appropriately considered in the UFSAR and Duke Energy has concluded that the proposed changes do not increase the possibility that a damaging tornado will strike the site or increase the consequences from a damaging tornado.

The Standby Shutdown Facility (SSF) structure has been designed for tornado related effects per the requirements of RG [Regulatory Guide] 1.76 Revision 1 or RG 1.76 Revision 0, with exceptions as noted in UFSAR Section 9.6.3.1 and UFSAR Table 9-17. The portions of the SSF piping and control cables that traverse from the tornado protected SSF structure to the Cask Decontamination Tank room (CDTR) are either enclosed in tornado protected trenches or are sufficiently direct buried to prevent tornado damage. The West Penetration room (WPR) and CDTR walls have been physically upgraded to the requirements of RG 1.76 Revision 1 to resist the effects of tornado wind and differential pressure. The existing SSF related piping and control cables routed through the WPR and CDTR, other systems and components necessary for the SSF to function, and the proposed pathway of committed modifications necessary to improve the ability of the SSF to mitigate a tornado are physically protected or are evaluated with TORMIS. The TORMIS evaluation meets the acceptance criteria on a unit specific basis. As a result, there is reasonable assurance that a tornado missile will not prohibit the SSF system from fulfilling its tornado LB or other functions.

The SFP suction path to the HPI system currently described in UFSAR Section 3.2.2 is being deleted from the LB. The existing piping configuration that connects the spent fuel pool suction path to the HPI system will remain, but will no longer be credited. This will eliminate an alternative plant configuration that, when aligned and operated, involves significant operator actions outside of the control room. Availability of the path provides no appreciable benefit with respect to the overall station tornado mitigation capability. Previously, the BWST [borated water storage tank] was not fully tornado missile protected and the SFP provided another source of HPI

suction if the BWST was unavailable. The BWST has since been modified to withstand tornado missiles defined in UFSAR Section 3.8.4, such that the SFP is not expected to be needed for the HPI pumps. With the new tornado LB crediting the SSF as the assured mitigation path following a tornado, the HPI system and any affiliated suction source are no longer necessary for meeting the tornado success criteria.

Overall, the changes proposed will increase assurance that safe shutdown (SSD) can be achieved following a damaging tornado. In conclusion, the changes will collectively enhance the station's overall design and safety margin; therefore, the probability or consequences of accidents previously evaluated are not significantly increased.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

*Justification:* This LAR credits the SSF as the deterministically protected path for the mitigation of tornadoes. The previously credited spent fuel pool suction path to the HPI system currently described in UFSAR Section 3.2.2 is being removed from the LB. The suction path is not fully protected from the effects of a tornado and this change eliminates an alternative plant configuration that, when aligned and operated, involves significant operator actions outside of the control room. Availability of the path provides no appreciable benefit with respect to the overall station tornado mitigation capability. With the new tornado LB, crediting the SSF as the assured mitigation path following a tornado, the HPI system and any affiliated suction source are no longer necessary for meeting the tornado success criteria. The SSF is credited for establishing and maintaining Secondary Side Decay Heat Removal (SSDHR) and Reactor Coolant Makeup (RCMU) up to 72 hours following a damaging tornado. Committed modifications improve the ability of the SSF systems to perform their functions following a damaging tornado. The modifications will be designed and installed in accordance with current LB codes/requirements. Failure analyses will ensure no new failure modes and effects are introduced. This will ensure that no new failure mechanisms, malfunctions or accident initiators not already considered in the design and LB are introduced.

3. Does the proposed amendment involve a significant reduction in the margin of safety?

*Response:* No.

*Justification:* The SSF is credited for establishing and maintaining SSDHR and RCMU up to 72 hours following a damaging tornado. Currently, the LB is a combination of probabilistic, diversity, and defense-in-depth strategies addressing the capability to provide SSD of the ONS units. This proposed change establishes the SSF as a deterministic strategy. The previously credited spent fuel pool suction path to the HPI system currently described in UFSAR Section 3.2.2 is being removed from the LB. The suction path is not fully protected from the effects of a tornado and this change eliminates an alternative

plant configuration that, when aligned and operated, involves significant operator actions outside of the control room. Availability of the path provides no appreciable benefit with respect to the overall station tornado mitigation capability. With the new tornado LB crediting the SSF as the assured mitigation path following a tornado, the HPI system and any affiliated suction source are no longer necessary for meeting the tornado success criteria. The proposed tornado LB will collectively enhance the station's overall design and safety margin; therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Kate Nolan, Deputy General Counsel, Duke Energy Carolinas, 550 South Tryon Street, Charlotte, NC 28202.

*NRC Branch Chief:* Michael T. Markley.

#### **Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation**

*Duke Energy Carolinas, LLC, Docket Nos. 50-269, 50-270, and 50-287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina*

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A "potential party" is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Hearings and Administration, Office of the General

Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov*, respectively.<sup>1</sup> The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requester has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order<sup>2</sup> setting forth terms and conditions to prevent the unauthorized or inadvertent

<sup>1</sup> While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's "E-Filing Rule," the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

<sup>2</sup> Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether

granting or denying access) is governed by 10 CFR 2.311.<sup>3</sup>

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to

minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule

for processing and resolving requests under these procedures.  
*It is so ordered.*

Dated at Rockville, Maryland, this 12th day of March, 2019.  
For the Nuclear Regulatory Commission.

**Annette L. Vietti-Cook,**  
*Secretary of the Commission.*

**ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING**

Day	Event/activity
0 .....	Publication of <b>Federal Register</b> notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10 .....	Deadline for submitting requests for access to SUNSI with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60 .....	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20 .....	NRC staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25 .....	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30 .....	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40 .....	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A .....	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3 .....	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28 .....	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI contentions by that later deadline.
A + 53 .....	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60 .....	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60 .....	Decision on contention admission.

[FR Doc. 2019-04959 Filed 4-1-19; 8:45 am]

**BILLING CODE 7590-01-P**

**NUCLEAR REGULATORY COMMISSION**

[NRC-2018-0194]

**Information Collection: Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Renewal of existing information collection; request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material."

**DATES:** Submit comments by June 3, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0194. Address questions about docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301-287-9127; email: [Jennifer.Borges@nrc.gov](mailto:Jennifer.Borges@nrc.gov).

For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T6-A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and

<sup>3</sup>Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR

46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as

applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Obtaining Information and Submitting Comments**

*A. Obtaining Information*

Please refer to Docket ID NRC-2018-0194 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2018-0194.
- *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](mailto:pdr.resource@nrc.gov). The supporting statement and NRC Form 653, 653A and 653B are available in ADAMS under Accession Nos. ML18323A028 and ML19037A053, respectively.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: [Infocollects.Resource@nrc.gov](mailto:Infocollects.Resource@nrc.gov).

*B. Submitting Comments*

Please include Docket ID NRC-2018-0194 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in

comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

**II. Background**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Title 10 of the *Code of Federal Regulations* (CFR), part 32, “Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.”

2. *OMB approval number:* 3150-0001.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Form 653, NRC Form 653A, and NRC Form 653B.

5. *How often the collection is required or requested:* There is a one-time submittal of information to receive a certificate of registration for a sealed source and/or device. Certificates of registration for sealed sources and/or devices can be amended at any time. In addition, licensee recordkeeping must be performed on an on-going basis, and reporting of transfer of byproduct material must be reported every calendar year, and in some cases, every calendar quarter.

6. *Who will be required or asked to respond:* All specific licensees who manufacture or initially transfer items containing byproduct material for sale or distribution to general licensees, or persons exempt from licensing, medical use product distributors to specific licensees, and those requesting a certificate of registration for a sealed source and/or device.

7. *The estimated number of annual responses:* 3,197 [2,637 reporting + 252 recordkeepers + 308 third-party recordkeepers].

8. *The estimated number of annual respondents:* 617 (180 NRC licenses, registration certificate holder, and 437 Agreement States licensees and registration certificate holders).

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 66,585 (18,405 reporting + 1,112 recordkeeping + 47,068 third-party).

10. *Abstract:* 10 CFR part 32, establishes requirements for specific licenses for the introduction of byproduct material into products or materials and transfer of the products or materials to general licensees, or persons exempt from licensing, medical use product distributors to specific licensees, and those requesting a certificate of registration for a sealed source and/or device. It also prescribes requirements governing holders of the specific licenses. Some of the requirements are for information which must be submitted in an application for a certificate of registration for a sealed source and/or device, records which must be kept, reports which must be submitted, and information which must be forwarded to general licensees and persons exempt from licensing. As mentioned, 10 CFR part 32 also prescribes requirements for the issuance of certificates of registration (concerning radiation safety information about a product) to manufacturers or initial transferors of sealed sources and devices. Submission or retention of the information is mandatory for persons subject to the 10 CFR part 32 requirements. The information is used by the NRC to make licensing and other regulatory determinations concerning the use of radioactive byproduct material in products and devices.

**III. Specific Requests for Comments**

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 28th day of March 2019.

For the Nuclear Regulatory Commission.

**David C. Cullison,**

*NRC Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 2019-06331 Filed 4-1-19; 8:45 am]

**BILLING CODE 7590-01-P**

## POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019-108 and CP2019-117; MC2019-109 and CP2019-118]

### New Postal Products

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* April 4, 2019.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202-789-6820.

### SUPPLEMENTARY INFORMATION:

#### Table of Contents

- I. Introduction
- II. Docketed Proceeding(s)

#### I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also

establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.<sup>1</sup>

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

### II. Docketed Proceeding(s)

1. *Docket No(s):* MC2019-108 and CP2019-117; *Filing Title:* USPS Request to Add Priority Contract 515 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* March 27, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.*, and 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* April 4, 2019.

2. *Docket No(s):* MC2019-109 and CP2019-118; *Filing Title:* USPS Request to Add Parcel Return Service Contract 15 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* March 27, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.*, and 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* April 4, 2019.

This Notice will be published in the **Federal Register**.

**Stacy L. Ruble,**

*Secretary.*

[FR Doc. 2019-06350 Filed 4-1-19; 8:45 am]

**BILLING CODE 7710-FW-P**

## POSTAL SERVICE

### Product Change—Priority Mail Negotiated Service Agreement

**AGENCY:** Postal Service™.

<sup>1</sup> See Docket No. RM2018-3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19-22 (Order No. 4679).

**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

**DATES:** *Date of required notice:* April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Reed, 202-268-3179.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 28, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 516 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019-110, CP2019-119.

**Elizabeth Reed,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019-06370 Filed 4-1-19; 8:45 am]

**BILLING CODE 7710-12-P**

## POSTAL SERVICE

### Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

**AGENCY:** Postal Service™.

**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

**DATES:** *Date of required notice:* April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Reed, 202-268-3179.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 28, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 57 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019-113, CP2019-122.

**Elizabeth Reed,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019-06376 Filed 4-1-19; 8:45 am]

**BILLING CODE 7710-12-P**

**POSTAL SERVICE****Product Change—Priority Mail Express Negotiated Service Agreement**

**AGENCY:** Postal Service™.  
**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

**DATES:** *Date of required notice:* April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Reed, 202–268–3179.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 28, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express Contract 72 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019–112, CP2019–121.

**Elizabeth Reed,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019–06372 Filed 4–1–19; 8:45 am]

**BILLING CODE 7710–12–P**

**POSTAL SERVICE****Product Change—Priority Mail Negotiated Service Agreement**

**AGENCY:** Postal Service™.  
**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

**DATES:** *Date of required notice:* April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Reed, 202–268–3179.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 28, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 517 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019–111, CP2019–120.

**Elizabeth Reed,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019–06371 Filed 4–1–19; 8:45 am]

**BILLING CODE 7710–12–P**

**POSTAL SERVICE****Product Change—Parcel Return Service Negotiated Service Agreement**

**AGENCY:** Postal Service™.  
**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

**DATES:** *Date of required notice:* April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Reed, 202–268–3179.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 27, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Parcel Return Service Contract 15 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019–109, CP2019–118.

**Elizabeth Reed,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019–06367 Filed 4–1–19; 8:45 am]

**BILLING CODE 7710–12–P**

**POSTAL SERVICE****Product Change—Priority Mail Negotiated Service Agreement**

**AGENCY:** Postal Service™.  
**ACTION:** Notice.

**SUMMARY:** The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

**DATES:** *Date of required notice:* April 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Reed, 202–268–3179.

**SUPPLEMENTARY INFORMATION:** The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on March 27, 2019, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 515 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2019–108, CP2019–117.

**Elizabeth Reed,**

*Attorney, Corporate and Postal Business Law.*

[FR Doc. 2019–06366 Filed 4–1–19; 8:45 am]

**BILLING CODE 7710–12–P**

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34–85430; File No. SR–NYSEArca–2019–14]

**Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Relating to Certain Changes Regarding Investments of the PGIM Ultra Short Bond ETF Under NYSE Arca Rule 8.600–E**

March 27, 2019.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the “Act”)<sup>2</sup> and Rule 19b–4 thereunder,<sup>3</sup> notice is hereby given that, on March 13, 2019, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes certain changes regarding investments of the PGIM Ultra Short Bond ETF (the “Fund”), a series of PGIM ETF Trust (the “Trust”), under NYSE Arca Rule 8.600–E (“Managed Fund Shares”). The proposed change is available on the Exchange's website at [www.nyse.com](http://www.nyse.com), at the principal office of the Exchange, and at the Commission's Public Reference Room.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b–4.

*A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes certain changes, described below under "Application of Generic Listing Requirements," regarding investments of the Fund. The shares ("Shares") of the Fund commenced trading on the Exchange on April 10, 2018 pursuant to the generic listing standards under Commentary .01 to NYSE Arca Rule 8.600-E ("Managed Fund Shares").<sup>4</sup> The Commission has previously approved two proposed rule changes regarding certain changes that would result in the portfolio for the Fund not meeting all of the "generic" listing requirements of Commentary .01 to NYSE Arca Rule 8.600-E applicable to the listing of Managed Fund Shares.<sup>5</sup>

PGIM Investments LLC (the "Adviser") is the investment adviser for the Fund. PGIM Fixed Income (the "Subadviser"), a unit of PGIM, Inc., is the subadviser to the Fund. The Adviser and the Subadviser are indirect wholly-owned subsidiaries of Prudential Financial, Inc.<sup>6</sup>

<sup>4</sup> A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a-1) (the "1940 Act") organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Rule 5.2-E(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

<sup>5</sup> See Securities Exchange Act Release Nos. 83319 (May 24, 2018), 83 FR 25097 (May 31, 2018) (SR-NYSEArca-2018-15), (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to Continue Listing and Trading Shares of the PGIM Ultra Short Bond ETF under NYSE Arca Rule 8.600-E) ("First Prior Order"); 84818 (December 13, 2018) (SR-NYSEArca-2018-75) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Regarding the Listing and Trading of Shares of the PGIM Ultra Short Bond ETF) ("Second Prior Order") and, together with the First Prior Order, the "Prior Orders"). The First Prior Order stated that the Fund's portfolio would meet all requirements of Commentary .01 to NYSE Arca Rule 8.600-E except for those set forth in Commentary .01(a)(1), Commentary .01(b)(4) and Commentary .01(b)(5). The Second Prior Order stated that the Fund's portfolio would not meet the requirements of Commentary .01(e) to NYSE Arca Rule 8.600-E.

<sup>6</sup> The Trust is registered under the 1940 Act. On March 26, 2018, the Trust filed with the Commission Pre-Effective Amendment No. 1 to the Trust's registration statement on Form N-1A under the Securities Act of 1933 (15 U.S.C. 77a), and under the 1940 Act relating to the Fund (File Nos. 333-222469 and 811-23324) ("Registration Statement"). The Trust will file an amendment to

As stated in the First Prior Order, the investment objective of the Fund seeks to provide total return through a combination of current income and capital appreciation, consistent with preservation of capital. The Fund seeks to achieve its investment objective by investing primarily in a portfolio of U.S. dollar denominated short-term fixed, variable and floating rate debt instruments. Under normal market conditions,<sup>7</sup> the Fund invests at least 80% of its net assets (plus any borrowings for investment purposes) in a portfolio of financial instruments consisting of (i) the Principal Investment Instruments (as defined in the First Prior Order) and (ii) derivatives (as described in the Prior Orders) that (A) provide exposure to such Principal Investment Instruments, or (B) are used to enhance returns, manage portfolio duration, or manage the risk of securities price fluctuations, as described in the Prior Orders.

*Application of Generic Listing Requirements*

The Exchange proposes that, in addition to the requirement approved by the Commission in the First Prior Order that Private ABS/MBS (as defined below) will, in the aggregate, not exceed more than 20% of the total assets of the Fund,<sup>8</sup> the Fund will not invest more than 20% of the Fund's total assets in U.S. or foreign collateralized debt obligations ("CDOs").<sup>9</sup> The Exchange also proposes that Private ABS/MBS will not be required to comply with the requirements of Commentary .01(b)(4) to NYSE Arca Rule 8.600-E.<sup>10</sup>

the Registration Statement as necessary to conform to the representations in this filing. The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. See Investment Company Act Release No. 31095 (June 24, 2014) (File No. 812-14267).

<sup>7</sup> The term "normal market conditions" is defined in NYSE Arca Rule 8.600-E(c)(5).

<sup>8</sup> As described in the First Prior Order, among the Fund's Principal Investment Instruments are asset-backed securities ("ABS"), including mortgage-backed securities ("MBS"). The ABS (including MBS) in which the Fund invests include both (i) ABS (including MBS) issued by the U.S. Government, an agency of the U.S. Government, or a government sponsored entity ("GSE") and (ii) non-U.S. Government, non-agency, non-GSE and other privately issued ABS (including MBS) ("Private ABS/MBS").

<sup>9</sup> For purposes of this filing, CDOs will not be deemed to be ABS for purposes of the restriction on the Fund's holdings of Private ABS/MBS. See note 9, *infra*.

<sup>10</sup> Commentary .01(b)(4) provides that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio must be either: (a) From issuers that are required to file reports pursuant to Sections 13 and 15(d) of the Act; (b) from issuers that have a worldwide

The Fund's investments currently comply with the generic requirements set forth in Commentary .01 to Rule 8.600-E.

The Exchange is submitting this proposed rule change because the changes described in the preceding paragraph would not conform to the Exchange's representations regarding the Fund's investments as stated in the First Prior Order. In the First Prior Order, the Exchange stated that the Fund will not comply with the requirement in Commentary .01(b)(5) that investments in non-agency, non-government sponsored entity and privately issued mortgage-related and other asset-backed securities (*i.e.*, Private ABS/MBS) not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the portfolio, and, instead, that Private ABS/MBS, in the aggregate, may not exceed more than 20% of the total assets of the Fund.<sup>11</sup> As stated above, the Exchange proposes to amend this representation regarding the Fund's investments to provide that the Fund will not invest more than 20% of the Fund's total assets in Private ABS/MBS or more than 20% of the Fund's total assets in U.S. or foreign CDOs.<sup>12</sup> CDOs

market value of its outstanding common equity held by non-affiliates of \$700 million or more; (c) from issuers that have outstanding securities that are notes, bonds debentures, or evidence of indebtedness having a total remaining principal amount of at least \$1 billion; (d) exempted securities as defined in Section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country. In the First Prior Order, the Commission approved an exception from Commentary .01(b)(4) to provide that fixed income securities that do not meet any of the criteria in Commentary .01(b)(4) will not exceed 10% of the total assets of the Fund.

<sup>11</sup> Commentary .01(b)(5) to NYSE Arca Rule 8.600-E provides that non-agency, non-government sponsored entity and privately issued mortgage-related and other asset-backed securities components of a portfolio may not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the portfolio. In the First Prior Order, the Commission approved an exception from Commentary .01(b)(5) to permit the Fund's investments in Private ABS/MBS to not exceed 20% of the total assets of the Fund.

<sup>12</sup> For purposes of this proposed rule change, CDOs are excluded from the definition of ABS and, for purposes of this proposed rule change only, are comprised exclusively of collateralized loan obligations ("CLOs") and collateralized bond obligations ("CBOs"). CLOs are securities issued by a trust or other special purpose entity that are collateralized by a pool of loans by U.S. banks and participations in loans by U.S. banks that are unsecured or secured by collateral other than real estate. CBOs are securities issued by a trust or other special purpose entity that are backed by a diversified pool of fixed income securities issued by U.S. or foreign governmental entities or fixed income securities issued by U.S. or corporate issuers. CDOs are distinguishable from ABS because they are collateralized by bank loans or by corporate or government fixed income securities and not by

Continued

would be excluded from the 20% limit on Private ABS/MBS but would be subject to a separate limit of 20%, measured with respect to the total assets of the Fund.<sup>13</sup> The Exchange believes that this 20% limitation will help the Fund maintain portfolio diversification and will reduce manipulation risk.<sup>14</sup> In addition, the Fund's investment in CDOs will be subject to the Fund's liquidity procedures as adopted by the Board, and the Adviser does not expect that investments in CDOs of up to 20% of the total assets of the Fund will have any material impact on the liquidity of the Fund's investments.

In addition, the First Prior Order stated that the Fund will not comply with the requirement that securities that in aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria in Commentary .01(b)(4), and, instead, fixed income securities that do not meet any of the criteria in Commentary .01(b)(4) will not exceed 10% of the total assets of the Fund. As stated above, the Exchange proposes to amend this representation to state that the Private ABS/MBS, which will be limited to 20% of the Fund's total assets, will not be required to comply with the criteria in Commentary .01(b)(4)(a) through (e) to NYSE Arca Rule 8.600–E. Therefore, fixed income securities that do not meet the criteria in Commentary .01(b)(4) will not exceed 10% of the total assets of the Fund, excluding Private ABS/MBS.<sup>15</sup> CDOs also would not be subject to the criteria in Commentary .01(b)(4)(a) through (e) but would be subject to a

consumer and other loans made by non-bank lenders, including student loans.

<sup>13</sup> The Exchange notes that the Commission has approved a proposed rule change permitting investments by an issue of Managed Fund Shares to exclude CDOs from the 20% limit on Private ABS/MBS but subject CDOs to a separate limit of 10%, measured with respect to the total assets of the fund. See Securities Exchange Act Release No. 84047 (September 6, 2018), 83 FR 46200 (September 12, 2018) (SR–NASDAQ–2017–128) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, to List and Trade Shares of the Western Asset Total Return ETF).

<sup>14</sup> The Exchange notes that the Commission has approved a proposed rule change permitting an issue of Managed Fund Shares to hold up to 30% of the weight of the fixed income securities portion of the fund's portfolio to consist of non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities. See Securities Exchange Act Release No. 84826 (December 14, 2018), 83 FR 65386 (December 20, 2018) (SR–NYSEArca–2018–25) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, Regarding the Continued Listing and Trading of Shares of the Natixis Loomis Sayles Short Duration Income ETF).

<sup>15</sup> As noted above, CDOs would be excluded from the 20% limit on Private ABS/MBS but would be subject to a separate limit of 20%, measured with respect to the total assets of the Fund.

limit of 20%, measured with respect to the total assets of the Fund.

The Exchange notes that the Commission has previously approved the listing of Managed Fund Shares with similar investment objectives and strategies without imposing requirements that a certain percentage of such funds' securities meet one of the criteria set forth in Commentary .01(b)(4).<sup>16</sup>

Deviations from the generic requirements are necessary for the Fund to achieve its investment objective in a manner that is cost-effective and that maximizes investors' returns. Further, the proposed alternative requirements are narrowly tailored to allow the Fund to achieve its investment objective in manner that is consistent with the principles of Section 6(b)(5) of the Act. As a result, it is in the public interest to approve listing and trading of Shares of the Fund on the Exchange pursuant to the requirements set forth herein.

In addition, the Fund's investment in Private ABS/MBS and CDOs will be subject to the Fund's liquidity risk management program as approved by the Fund's board of directors.<sup>17</sup> The liquidity procedures generally include public disclosure by the Fund of its liquidity and redemption practices. The Fund's holdings in Private ABS/MBS and CDOs would be encompassed within the Fund's liquidity risk management program.

Except for the changes noted above, all other representations made in the Prior Orders remain unchanged. All terms referenced but not defined in this proposed rule change are defined in the Prior Orders.

## 2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) of the Act that an exchange have rules that are designed to

<sup>16</sup> See, e.g., Exchange Act Release Nos. 67894 (September 20, 2012) 77 FR 59227 (September 26, 2012) (SR–BATS–2012–033) (order approving the listing and trading of shares of the iShares Short Maturity Bond Fund); 70342 (September 6, 2013), 78 FR 56256 (September 12, 2013) (SR–NYSEArca–2013–71) (order approving the listing and trading of shares of the SPDR SSgA Ultra Short Term Bond ETF, SPDR SSgA Conservative Ultra Short Term Bond ETF and SPDR SSgA Aggressive Ultra Short Term Bond ETF).

<sup>17</sup> Rule 22e–4(b) under the 1940 Act requires, among other things, that a fund “adopt and implement a written liquidity risk management program that is reasonably designed to assess and manage its liquidity risk.” The rule is “designed to promote effective liquidity risk management throughout the open-end investment company industry, thereby reducing the risk that funds will be unable to meet their redemption obligations and mitigating dilution of the interests of fund shareholders.” See Release Nos. 33–10233; IC–32315; File No. S7–16–15 (October 13, 2016).

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, in general, to protect investors and the public interest.

As described above, deviations from the generic requirements of Commentary .01(b) to Rule 8.600–E are necessary for the Fund to achieve its investment objective in a manner that is cost-effective and that maximizes investors' returns. Further, the proposed alternative requirements are narrowly tailored to allow the Fund to achieve its investment objective in manner that is consistent with the principles of Section 6(b)(5) of the Act. As a result, it is in the public interest to approve continued listing and trading of Shares of the Fund on the Exchange pursuant to the requirements set forth herein.

The Fund will not meet the requirement that at least 90% of the fixed income weight of the Fund's portfolio meet one of the criteria in Commentary .01(b)(4)(a) through (e) to Rule 8.600–E because some Private ABS/MBS cannot satisfy the criteria in Commentary .01(b)(4)(a) through (e). The Exchange proposes, in the alternative, to require that Fund's investments in fixed income securities that do not meet the criteria in Commentary .01(b)(4) will not exceed 10% of the total assets of the Fund, excluding Private ABS/MBS.<sup>18</sup> CDOs also would not be subject to the criteria in Commentary .01(b)(4)(a) through (e) but would be subject to a limit of 20% measured with respect to the total assets of the Fund. The Exchange believes that this alternative limitation is appropriate because the criteria in Commentary .01(b)(4)(a) through (e) do not appear to be designed for structured finance vehicles such as Private ABS/MBS, and the overall weight of Private ABS/MBS held by the Fund will be limited to 20% of the total assets of the Fund's portfolio, as described above.

As discussed above, the Exchange proposes that CDOs will not be deemed to be included in the definition of ABS for purposes of the limitation in Commentary .01(b)(5) to NYSE Arca Rule 8.600–E and, as a result, will not be subject to the restriction on aggregate holdings of Private ABS/MBS. However, the Fund's holdings in CDOs will be limited such that they do not account, in the aggregate, for more than 20% of the total assets of the Fund. The Exchange believes that the 20% limit on the Fund's holdings in CDOs will help to ensure that the Fund maintains a

<sup>18</sup> See note 13, *supra*.

diversified portfolio and will mitigate the risk of manipulation. In addition, the Fund's investment in CDOs will be subject to the Fund's liquidity procedures as adopted by the Board,<sup>19</sup> and the Adviser does not expect that investments in CDOs of up to 20% of the total assets of the Fund will have any material impact on the liquidity of the Fund's investments.

#### *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 purpose of the Act. The Exchange believes that the proposed rule change will facilitate listing and trading of shares of another actively managed ETF that principally holds fixed income securities, and that will enhance competition among market participants, to the benefit of investors and the marketplace.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- A. By order approve or disapprove the proposed rule change, or
- B. institute proceedings to determine whether the proposed rule change should be disapproved.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### *Electronic Comments*

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or

- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEArca-2019-14 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-NYSEArca-2019-14. 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-NYSEArca-2019-14 and should be submitted on or before April 23, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>20</sup>

**Eduardo A. Aleman,**

*Deputy Secretary.*

[FR Doc. 2019-06313 Filed 4-1-19; 8:45 am]

**BILLING CODE 8011-01-P**

## **SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-85429; File No. SR-NYSEAMER-2019-06]

### **Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rules 900.3NY, 925.1NY, and 971.1NY**

March 27, 2019.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the "Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that on March 14, 2019, NYSE American LLC ("NYSE American" or the "Exchange") 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### **I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes to to [sic] amend Rules 900.3NY (Orders Defined) and 925.1NY (Market Maker Quotes) to add a new order type and quotation designation and to make conforming changes to Rule 971.1NY (Single-Leg Electronic Cross Transactions). The proposed rule change is available on the Exchange's website at [www.nyse.com](http://www.nyse.com), at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### **II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

<sup>19</sup> See note 15, *supra*.

<sup>20</sup> 17 CFR 200.30-3(a)(12).

*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 modify Rules 900.3NY and 925.1NY to add a new order type and quotation designation as described herein. The Exchange also proposes to make conforming changes to these rules, as well as to Rule 971.1NY regarding the Customer Best Execution Auction or CUBE for single-leg options (the "CUBE Auction" or "Auction"), to reflect the impact of the proposed order type and quotation designation on the auction mechanism.

The proposed order type and quote designation are substantially identical to those utilized on NYSE Arca, Inc. ("NYSE Arca").<sup>4</sup> However, in addition to addressing the impact of the proposed changes on the CUBE Auction (which NYSE Arca does not have), the proposal differs from the NYSE Arca rules to reflect the Exchange's allocation rules, which differ from NYSE Arca's price-time priority allocation scheme. Pursuant to Rule 964NY (Display, Priority and Order Allocation—Trading Systems), at each price point, the Exchange affords Customer orders priority over same-priced non-Customer orders.<sup>5</sup> Specifically, the Exchange ranks and allocates Customer orders at the same price in time priority and, after all Customer orders are executed at a price, non-Customer orders at the same price are allocated on a size pro rata basis.<sup>6</sup> Aside from the difference in how

the repricing interest is prioritized and allocated on the Exchange, the proposed order type and quotation designation function the same as on NYSE Arca. The proposed order type and quote designation are designed to operate seamlessly with the CUBE Auction as well as the Exchange's Customer and price-time priority model.

Repricing PNP Order ("RPNP")

Rule 900.3NY(p) provides that a PNP (Post No Preference) Order is eligible to interact solely with interest on the Exchange, will not route, and will cancel if it locks or crosses the NBBO.<sup>7</sup> PNP Orders provide market participants control over how their orders interact with contra-side liquidity.<sup>8</sup>

The Exchange proposes to add an order type—RPNP—that builds on the existing PNP Order functionality to allow for repricing (rather than cancellation) as described below. As proposed, a RPNP is a PNP Order that would be repriced instead of cancelled after trading with interest in the Consolidated Book<sup>9</sup> if it would lock or cross the NBBO.<sup>10</sup> As proposed, an RPNP may only be entered as a Day Order.<sup>11</sup> The Exchange also proposes to

(c) (providing for executions of orders and quotes on the Exchange).

<sup>7</sup> See Rule 900.3NY(p) (providing that a PNP Order "is a Limit Order to buy or sell that is to be executed in whole or in part on the Exchange, and the portion not so executed is to be ranked in the Consolidated Book, without routing any portion of the order to another market center; provided, however, the Exchange shall cancel a PNP Order that would lock or cross the NBBO"). The Exchange proposes to capitalize the "Market Center" as used in paragraph (p) of the Rule, which is a defined term in Rule 900.2NY(36). See proposed Rule 900.3NY(p).

<sup>8</sup> A PNP Order may also be designated as an Immediate-Or-Cancel Order ("IOC Order") and, when such designation is made, the IOC Order behavior trumps the PNP Order behavior. In other words, the portion of a PNP IOC Order that is not executed immediately will cancel rather than potentially be ranked in the Consolidated Book. The Exchange proposes to modify the definition of a PNP Order to specify the behavior of a PNP IOC Order. See proposed Rule 900.3NY(p) (providing in relevant part that, "[a] PNP Order that is designated as IOC Order will be treated as an IOC Order (per Rule 900.3NY(k)), such that any unexecuted portion shall cancel"). See also 900.3NY(k) (providing that an IOC Order "is a Limit Order that is to be executed in whole or in part on the Exchange as soon as such order is received, and the portion not so executed is to be canceled").

<sup>9</sup> See Rule 900.2NY(14) (defining the Consolidated Book (or "Book") as the Exchange's electronic book of limit orders for the accounts of Customers and broker-dealers, and Quotes with Size, all of which are ranked and maintained in accordance with the rules of priority as provided in Rule 964NY).

<sup>10</sup> See proposed Rule 900.3NY(p)(1).

<sup>11</sup> See proposed Rule 900.3NY(p)(1). This proposed rule text is based on the last sentence of NYSE Arca Rule 6.62–O(p)(1) with a substantive difference not to reference Reserve Orders, which are not available on the Exchange.

amend Rule 900.3NY(p) to provide that an RPNP received during pre-open or during a trading halt will be treated as a PNP Order (*i.e.*, as a Limit Order and will not reprice) for purposes of participating in opening auctions or re-opening auctions. This proposed rule text is based on the last sentence of NYSE Arca Rule 6.62–O(p) without any differences.

Proposed Rule 900.3NY(p)(1)(A) would provide that a RPNP to buy (sell) that would lock or cross the NBO (NBB) would be displayed at a price one MPV below (above) the NBO (NBB). This proposed rule would further provide that if the NBO (NBB) moves up (down), the display price of the RPNP to buy (sell) and the undisplayed price at which it is eligible to trade would be continuously adjusted, up (down) to the limit price of the RPNP.<sup>12</sup> Proposed Rule 900.3NY(p)(1)(A)(i) would provide that a RPNP to buy (sell) that is displayed at a price one MPV below (above) the NBO (NBB) would be eligible to trade at the NBO (NBB), up (down) to the limit price of the RPNP; provided, however, that if the NBO (NBB) updates to lock or cross the RPNP's display price, such RPNP would trade at its display price.<sup>13</sup> Proposed Rule 900.3NY(p)(1)(A)(ii) would further provide that each time there is an update to the RPNP's price, the RPNP would be ranked with other eligible interest at that price, and would trade at each price, to the extent possible, pursuant to Rule 964NY.<sup>14</sup> For example, at the same price (including an updated (e)price), a RPNP submitted on behalf of a Customer would have first priority over non-Customer orders. The Exchange believes that this proposed handling of RPNPs would respect and preserve the Exchange's Customer priority and pro rata allocation model.

To avoid accepting RPNPs priced too far through the NBBO, the Exchange proposes to limit the extent to which it

<sup>12</sup> This proposed rule text is based on NYSE Arca Rule 6.62–O(p)(1)(A). The proposed RPNP also operates in substantially the same manner as the Non-Routable Limit Order available on the NYSE Arca's equities market, which, like the RPNP, reprices if it would lock or cross a protected quotation of an Away Market or trade through a protected quotation. See NYSE Arca Rule 7.31–E(e)(1).

<sup>13</sup> This proposed rule text is based on NYSE Arca Rule 6.62–O(p)(1)(A)(i) with a substantive difference not to reference that such orders would trade in time priority behind other eligible interest displayed at that price because the Exchange operates on a pro rata allocation model.

<sup>14</sup> See proposed Rule 900.3NY(p)(1)(A)(ii). This proposed rule text is based on NYSE Arca Rule 6.62–O(p)(1)(A)(ii) with a substantive difference to cross reference the Exchange's allocation model under Rule 964NY rather than NYSE Arca's price-time allocation model.

<sup>4</sup> See Securities Exchange Act Release Nos. 84451 (October 18, 2018), 83 FR 53692 (October 24 2018) ("NYSE Arca Repricing Notice"); 84737 ("NYSE Arca Repricing Approval Order") [sic] (December 6, 2018), 83 FR 63919 (December 12, 2018) (SR–NYSEArca–2018–74) ("NYSE Arca Repricing Approval Order") (approving adoption of MMRP, per NYSE Arca Rule 6.37A–O(a)(3)(C) and (a)(4)(B), and RPNP, per NYSE Arca Rule 6.62–O(p)(1)). The Exchanges notes that the NYSE Arca Repricing Approval Order also included an order type and quotation designation that would reprice if it would remove liquidity (*i.e.*, a RALO and MMALO, respectively), which are not being proposed by the Exchange.

<sup>5</sup> The term "non-Customers" includes Market Makers, Firms, Professional Customers and Non-ATP Holder Market Makers.

<sup>6</sup> See Rule 964NY(b)(2)(A) (providing that "if there is more than one highest bid for a Customer account or more than one lowest offer for a Customer account, then such bids or offers, respectively, will be ranked based on time priority"); and (b)(2)(B)–(D). Per Rule 964NY(b)(2)(D), for example, "[i]f there is more than one highest bid or more than one lowest offer in the Consolidated Book for the account of a non-Customer, then such bids or offers will be afforded priority on a 'size pro rata' basis, and will comprise the 'size pro rata pool'". See also Rule 964NY(b)(3) (setting forth size pro rata allocation method) and

would reprice such interest.<sup>15</sup> As proposed, an incoming RPNP would be cancelled after trading with eligible interest (if any) if its limit price to buy (sell) is more than a configurable number of MPVs above (below) the initial display price (on arrival) of the RPNP. The Exchange would determine the configurable number of MPVs, which would be announced by Trader Update.<sup>16</sup>

The Exchange believes the proposed RPNP would give market participants more flexibility and control over the circumstances under which their orders trade with contra side-interest, while ensuring that RPNPs priced too far through the contra-side NBBO would be rejected. The Exchange believes the proposed RPNP would assist market participants in maximizing opportunities for execution (as such orders would reprice rather than reject) while encouraging the provision of greater liquidity to the market, which would contribute to public price discovery.

\* \* \* \* \*

The following examples illustrate the proposed RPNP order type and how it would function under the Exchange's allocation model.

#### RPNP Example 1 (the MPV is \$0.01)

BOX 20 × 1.15 – 1.23 × 20  
BD1 B 50 @1.25 RPNP  
BD2 B 10 @1.26 RPNP  
BD3 B 15 @1.27 RPNP  
Specialist<sup>17</sup> 30 × 1.24 – 1.30 × 10 MMRP  
BD4 S 15 Mkt  
MM 100 × 1.20 – 1.25 × 30 MMRP  
BD5 S 10 Mkt  
Cust6 S 40 Mkt

#### Expected Result

BOX NBO @1.23  
BD1, 2, 3 and Specialist all display @ 1.22 (priced back one MPV from the NBO) and are eligible to trade @1.23 due to BOX offer @1.23  
BD4 sells 15 to BD1 @1.23 (leaving BD1 with 35)  
MM 1.25 offer does not trade (prohibited by BOX offer @1.23)  
BD5 sells 10 to BD1 @1.23 (leaving BD1 with 25)

<sup>15</sup> See proposed Rule 900.3NY(p)(1)(B). This proposed rule text is based on NYSE Arca Rule 6.62–O(p)(1)(B) without any differences.

<sup>16</sup> For example, in a Penny Pilot issue, if the local best offer is 0.99 and the away best offer is 1.00 with a configuration set to 3 MPV, a RPNP to buy at 1.03 or greater would trade with the local offer at 0.99 and any remaining interest will be cancelled (because the initial display price would be 0.99 which is 4 MPVs away from its limit price).

<sup>17</sup> A Specialist is a Market Maker on the Exchange that has heightened obligations in exchange for certain rights and privileges. See Rule 927NY. For example, Specialists may receive a participation entitlement, provided they are quoting at the NBBO. See, e.g., Rule 964NY(b)(2)(C).

Cust6 sells 25 to BD1 (exhausting BD1), 10 to BD2 (exhausting BD2), 5 to BD3 @1.23 (exhausting Cust6), in price-time priority because BD1, BD2 and BD3 are trading at an undisplayed price (The Specialist, which is eligible to trade @1.23 but displayed at 1.22, is not entitled to an allocation guarantee because it is not quoting (displayed) at the NBBO)<sup>18</sup>

#### RPNP Example 2 (the MPV is \$0.01)

BOX 20 × 1.15 – 1.26 × 20  
BD1 B 50 @1.25 RPNP  
Cust1 B 10 @1.25 RPNP  
BD3 B 15 @1.25 RPNP  
Specialist 30 × 1.25 – 1.30 × 10 MMRP  
BD4 S 15 Mkt  
BD5 S 10 Mkt  
Cust6 S 40 Mkt

#### Expected Result

BOX NBO @1.26  
BD1, Cust1, BD3 and Specialist display @limit price of 1.25 (no need to reprice because already one MPV away from the NBO) and will trade size pro rata with Cust priority and Specialist resulting in:  
BD4 sells 10 to Cust1, 5 to Specialist @ 1.25 (Specialist gets 100% of 5 lots or smaller)<sup>19</sup>  
BD5 sells 4 to Specialist @1.25 (i.e., 40%)<sup>20</sup> and 5 to BD1 and 1 to BD3 @ 1.25, pursuant to size pro rata allocation provided for in Rule 964NY(b)(3)  
Cust6 sells 16 to Specialist @1.25 (i.e., 40%)<sup>21</sup> and 18 to BD1 and 6 to BD3 @1.25, pursuant to size pro rata allocation provided for in Rule 964NY(b)(3)

#### Market Maker—Repricing Quotation (“MMRP”)

Current Rule 925.1NY(a) defines Market Maker quotes, including quotations designated as Market Maker—Light Only (“MMLO”), and specifies how such quotes are processed when a series is open for trading. The Exchange proposes to modify Rule 925.1NY(a) to add a new quote designation—MMRP—to provide market makers with the same functionality for their quotations as are proposed for

<sup>18</sup> See Rule 964NY(b)(2)(C) (regarding Specialist 40% participation guarantee).

<sup>19</sup> See Rule 964NY(b)(2)(C)(iv) (providing that “[f]or all orders of five (5) contracts or fewer, the Primary Specialist (as defined in Rule 964.2NY(a)) will be allocated the balance after any allocation to Customers, not to exceed the size of the Primary Specialist’s quote, provided the Primary Specialist is quoting at the NBBO, and the order was not originally allocated to a Directed Order Market Maker”).

<sup>20</sup> See *supra* note 18.

<sup>21</sup> *Id.*

orders entered on the Exchange.<sup>22</sup> The proposed quotation designation is similar to how the proposed RPNP would function and would enable Market Makers to exert greater control over how their quotes would interact with contra-side liquidity, while affording them more opportunities to provide liquidity.

As proposed, an incoming or resting quotation designated as MMRP would never display at a price that locks or crosses the NBBO.<sup>23</sup> Instead, after trading with interest in the Consolidated Book, an incoming MMRP to buy (sell) that locks or crosses the NBO (NBB) would be displayed at a price that is one MPV below (above) the NBO (NBB).<sup>24</sup> If the NBO (NBB) moves up (down), the display price of the MMRP to buy (sell) and the undisplayed price at which it is eligible to trade would be continuously adjusted, up (down) to the MMRP’s limit price.<sup>25</sup>

Similar to the proposed RPNP, an MMRP to buy (sell) that is displayed at a price one MPV below (above) the NBO (NBB) would trade at the NBO (NBB); provided, however, that if the NBO (NBB) updates to lock or cross the MMRP’s display price, such MMRP will trade at its display price.<sup>26</sup> Also consistent with the handling of RPNPs, the Exchange proposes that each time there is an update to the MMRP’s price, the MMRP would be ranked with other eligible interest at that price, and would trade at each price, to the extent possible, pursuant to Rule 964NY.<sup>27</sup> The

<sup>22</sup> See proposed Rule 925.1NY(a)(3)(B) and (a)(4)(B). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(3)(B) and (a)(4)(B). The Exchange proposes to delete reference to MMLO in current Rule 925.1NY(a)(3), which would be renumbered as Rule 925.1NY(a)(4), regarding the “[t]reatment of Market Maker Quotations,” as too restrictive in light of the proposed MMRP; instead, the Exchange proposes to separately describe the treatment of each quote type when a series is open for trading. See proposed Rule 925.1NY(a)(4).

<sup>23</sup> See proposed Rule 925.1NY(a)(3)(B) and (a)(4)(B). The Exchange also proposes to replace references to “another Market Center” with “the NBBO” to add clarity and consistency to the Rule. See proposed Rule 925.1NY(a)(4)(A), (a)(4)(C)(i), (a)(4)(D)(i)–(ii); see also NYSE Arca Rule 6.37A–O(a)(4)(C)(i), (D)(i)–(ii).

<sup>24</sup> See proposed Rule 925.1NY(a)(4)(B). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(B) without any differences.

<sup>25</sup> See *id.*

<sup>26</sup> See proposed Rule 925.1NY(a)(4)(B)(i). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(B)(i) with a substantive difference not to reference that such orders would trade in time priority behind other eligible interest displayed at that price because the Exchange operates on a pro rata allocation model.

<sup>27</sup> See proposed Rule 925.1NY(a)(4)(B)(ii). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(B)(ii) butcross references the Exchange’s allocation model under Rule 964NY rather than NYSE Arca’s price-time allocation model.

Exchange believes that this handling of MMRPs (which is consistent with the proposed handling of RPNPs) would respect and preserve the Exchange Customer priority and pro rata allocation model.

The Exchange notes that an MMRP may be submitted when a series is not open for trading (*i.e.*, during pre-open or a trading halt) and such MMRP would be eligible to participate in the opening auction and re-opening auction (as applicable) at the limit price of the MMRP.<sup>28</sup> Such MMRPs would not be repriced as an option series may not open (or re-open) if a quote is locked or crossed.<sup>29</sup>

To avoid accepting MMRPs priced too far through the NBBO, the Exchange proposes to limit the extent to which it would reprice such interest. Specifically, an incoming MMRP that has a limit price more than a configurable number of MPVs above (below) the initial display price (on arrival) would first trade with marketable interest in the Consolidated Book up (down) to the NBO (NBB) and any remaining balance would be cancelled.<sup>30</sup> Similarly, the Exchange would reject an incoming MMRP that does not trade (*i.e.*, because there is no marketable interest in the Consolidated Book) and has a limit price to buy (sell) that is more than a configurable number of MPVs above (below) the initial display price (on arrival) of the MMRP.<sup>31</sup> The Exchange would determine the applicable number of

MPVs and announce the configurable by Trader Update.<sup>32</sup>

The following trading example illustrates the operation of an MMRP under the Exchange's allocation model.

MMRP Example (the MPV is \$0.01)

MM 10 × 1.24 – 1.28 × 10  
ISE 20 × 1.25 – 1.32 × 20  
BD2 S 100 @1.23 RPNP  
MMRP 70 × 1.22 – 1.23 × 70  
BD3 S 50 @1.23 RPNP  
ISE Update 0 × 0 – 1.32 × 20

Expected Result

ISE NBB @1.25  
BD2 offer for 100 is eligible to trade @ 1.25 and will display @1.26 (priced back one MPV from the NBB)  
MMRP offer for 70 is eligible to trade @ 1.25 and will display @1.26 (priced back one MPV from the NBB)  
BD3 offer for 50 is eligible to trade @ 1.25 and will display @1.26  
ISE bid update to 0 results in the following size pro rata allocation (Rule 964NY(b)(3)):  
BD2 trades 5 with MM @1.24  
MMRP trades 3 with MM @1.24  
BD3 trades 2 with MM @1.24

The Exchange notes that absent the proposed MMRP, incoming quotes (or portions thereof) would reject or cancel if such quotes locked or crossed away markets, which aligns with the NMS plan for Options Order Protection And Locked/Crossed Market Plan ("Plan"), to which the Exchange is a party.<sup>33</sup> Thus, the Exchange believes that affording Market Makers the ability to designate quotes as MMRP affords Market Makers more certainty when

providing liquidity, while ensuring that MMRPs priced too far through the contra-side NBBO would cancel or reject after trading with any eligible interest on the Exchange.

In addition to adding new rule text to describe the function of the proposed MMRP<sup>34</sup> into existing rule text, the Exchange also proposes to streamline Rule 925.1NY, by re-organizing and re-numbering related text regarding the treatment of untraded incoming quotations. Specifically, the Exchange proposes to provide that "[a]ny untraded quantity of an incoming quotation will be added to the Consolidated Book, except in the circumstances specified below, which result in the remaining balance being cancelled,"<sup>35</sup> including when the incoming quotation "is not designated as MMRP" and locks or crosses the NBBO and when it is designated as MMLO and locks or crosses undisplayed interest.<sup>36</sup> Similarly, the Exchange would modify the rule providing that an incoming quotation that locks or crosses the NBBO would be rejected, provided "it is not designated as MMRP" and cannot trade with interest in the Consolidated Book at prices that do not trade through the NBBO.<sup>37</sup>

Further, to accommodate the new MMRP, the Exchange proposes to re-organize paragraph (a) of Rule 925.1NY, by re-locating text that a quote will never route from existing paragraph (a)(3) to paragraph (a)(2); adding new paragraph (a)(3) to provide that "[a] Market Maker may designate a quote as follows"; and re-numbering the balance of the paragraph to account for such changes.<sup>38</sup> In addition, as proposed, the description of the existing quote type MMLO would be re-numbered as paragraph (a)(3)(A), and the text would be streamlined to provide simply that "[o]n arrival, a quotation designated MMLO will trade with displayed interest in the Consolidated Book only. Once resting, the MMLO designation no longer applies and such quotation is

<sup>28</sup> See proposed Rule 925.1NY(a)(5). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(5) without any differences. The Exchange also proposes to make clear that "[a]ll resting quotations will be cancelled in the event of a trading halt." See *id.*

<sup>29</sup> See Rule 952NY(b)(E) (providing in relevant part, that "[i]f the System does not open a series with an Auction Process, the System shall open the series for trading after receiving notification of an initial uncrossed NBBO disseminated by OPRA for the series . . .").

<sup>30</sup> See proposed Rule 925.1NY(a)(4)(C)(iii). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(C)(iii) without any differences.

<sup>31</sup> See proposed Rule 925.1NY(a)(4)(D)(iii). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(D)(iii) without any differences. The Exchange notes that incoming MMRPs that fail the MPV check would be rejected while similarly-priced RPNPs would be accepted and then cancelled. The Exchange notes that this is a distinction without a difference and simply reflects an operational difference in how the Exchange evaluates these types of interest. The Exchange also proposes to re-locate text that is currently at the end of this provision to the beginning, such that the Rules states that "[a]n incoming quotation will be rejected, and the Exchange will cancel the Market Maker's current quotation on the same side of the market, if" as the Exchange believes this would streamline the Rule making it easier to navigate and understand. See *id.* This proposed rule change is also based on NYSE Arca Rule 6.37A–O(a)(4)(D).

<sup>32</sup> See proposed Rule 925.1NY (a)(4)(C)(iii). For example, in a Penny Pilot issue, if the local best offer is 0.99 and the away best offer is 1.00 with a configuration set to 3 MPV, a MMRP to buy at 1.03 or greater would trade with the local offer at 0.99 and any remaining interest will be cancelled (because the initial display price would be 0.99 which is 4 MPVs away from its limit price). Because the MMRP is cancelled, the Exchange would also cancel the opposite-side quote for that Market Maker. See Rule 925.1NY (a)(4)(B)(or, as renumbered, proposed Rule 925.1NY(a)(4)(C)) (providing, "[w]hen such quantity of an incoming quotation is cancelled, the Exchange will also cancel the Market Maker's current quotation on the opposite side of the market"); see also NYSE Arca Rule 6.37A–O(a)(4)(C).

<sup>33</sup> See Plan, dated April 14, 2009, available here, [http://www.optionsclearing.com/components/docs/clearing/services/options\\_order\\_protection\\_plan.pdf](http://www.optionsclearing.com/components/docs/clearing/services/options_order_protection_plan.pdf). See also Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009) (File No. 4–546) (order approving the Plan). The Plan obligates the participating exchanges to provide order protection, including addressing locked and crossed markets and the potential for trade-throughs in certain options classes. See *id.* Consistent with the Plan, the rules of the Exchange include prohibitions against trade-throughs and a pattern or practice of displaying certain quotations that lock or cross away markets. See, e.g., Rules 991NY, 992NY.

<sup>34</sup> See proposed Rule 925.1NY(a)(3)(B) and (a)(4)(B).

<sup>35</sup> See proposed Rule 925.1NY(a)(4)(C). This rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(C) without any differences.

<sup>36</sup> See proposed Rule 925.1NY(a)(4)(C)(i) and (ii). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(C)(i) and (ii) without any differences.

<sup>37</sup> See proposed Rule 925.1NY(a)(4)(D)(i). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(4)(D)(i) without any differences.

<sup>38</sup> See proposed Rule 925.1NY(a)(2)–(3). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(2)–(3), however it differs from NYSE Arca in that the Exchange is not adding a Market Maker—Add Liquidity Only quotation type. See NYSE Arca Rule 6.37A–O(a)(3)(B).

eligible to trade with displayed and undisplayed interest.”<sup>39</sup>

The Exchange notes that this proposal does not relieve a Market Maker of its continuous quoting or firm quote obligations pursuant to Rules 925.1NY and 970NY, respectively. Further, the Exchange notes that Market Makers would still be able to send orders in (and out of) classes to which they are appointed, as orders are not affected by this proposal.

#### RPNP/MMRP and the CUBE Auction

The Exchange proposes to modify Rule 971.1NY, regarding the single-leg CUBE Auction, to reflect current functionality relating to how the proposed RPNP/MMRP would potentially interact with a CUBE Auction.<sup>40</sup> The CUBE Auction is an electronic cross mechanism through which an ATP Holder (“Initiating Participant”) may initiate a CUBE Auction by submitting for execution a limit order it represents as agent on behalf of a public customer, broker dealer, or any other entity (the “CUBE Order”). The Initiating Participant, however, must guarantee the execution of the CUBE Order by submitting a contra-side order (“Contra Order”) representing principal interest or non-Customer interest it has solicited to trade solely with the CUBE Order at a single “stop price,” or a range of prices that will either “auto-match” all interest received during the auction or have a price limit on the matching (*i.e.*, “auto match limit price”).<sup>41</sup> Rule 971.1NY(b) sets for [sic] the conditions that must exist for a CUBE Auction to commence, including the range of permissible executions and that a CUBE Order will be rejected if the NBBO is crossed.<sup>42</sup> The CUBE Auction is designed to afford price improvement opportunities to CUBE Orders while interacting seamlessly with the Consolidated Book (*i.e.*, the Auction should not disrupt the Exchanges’ price-time priority model). ATP Holders may participate in the Auction with RFR Responses received during the Response Time Interval (“RTI”).<sup>43</sup>

<sup>39</sup> See proposed Rule 925.1NY(a)(3)(A). This proposed rule text is based on NYSE Arca Rule 6.37A–O(a)(3)(A) without any differences.

<sup>40</sup> The Exchange notes that Rule 971.2NY describes the Complex CUBE Auction which is not implicated by this filing.

<sup>41</sup> See Rule 971.1NY(a), (c)(1)(A)–(C).

<sup>42</sup> The Exchange proposes to modify Rule 971.1NY(b)(9) to reflect current functionality and make clear that a CUBE Order is today (and will be) rejected if NBBO is “locked or crossed” (emphasis added), which adds clarity and transparency to Exchange rules. See proposed Rule 971.1NY(b)(9).

<sup>43</sup> The RTI is subject to a random time period that is no less than 100 milliseconds and no more than 1 second. See Rule 971.1NY(c)(2)(B).

#### Modify Definition of RFR Responses To Include Resting Interest

Current Rule 971.1NY(c)(2)(C) provides that RFR Responses include GTX Orders submitted specifically to interact with the Auction<sup>44</sup> and unrelated interest that is on the opposite side of the CUBE Order and within the range of permissible executions.<sup>45</sup> Regarding the latter categories of RFR Responses (*i.e.*, unrelated quotes and orders), the Exchange proposes to clarify that current CUBE functionality treats interest “resting in the Consolidated Book when the Auction commences” as an RFR Response, provided the interest is on the opposite side of the CUBE Order and eligible to participate within the range of permissible executions specified in Rule 971.1NY(b)(1).<sup>46</sup>

This proposed change reflects current CUBE Auction functionality: Currently, standard Market Maker quotes as well as resting PNP Blind Orders (each a “PNPB”) which, when undisplayed are not included in the quoted market, are considered “unrelated quotes and orders” for purposes of Rule 971.1NY(b)(2)(C)(ii).<sup>47</sup> The proposed change would also account for the proposed RPNP/MMRP, which like a PNPB, may be resting undisplayed on the Book at the start of a CUBE Auction at a price with which a CUBE Order may execute. This proposed amendment is consistent with existing rule text regarding how the Exchange handles Customer interest resting at the start of an Auction (which could include a PNP Blind Order or a proposed RPNP). Specifically, such resting interest, at a price, gets first priority to trade with the CUBE Order ahead of Customer interest, at a price, that arrives during the

<sup>44</sup> See Rule 971.1NY(c)(2)(C)(i) (defining GTX Orders as non-routable order with a time-in-force contingency for the RTI that will not be displayed on the Consolidated Book and will cancel after trading (if at all) in the CUBE Auction).

<sup>45</sup> See Rule 971.1NY(c)(2)(C)(ii) (including as RFR Responses any “unrelated quotes and orders” in the same series as, and opposite side of, the CUBE Order that arrive during the RTI and eligible to participate within the range of permissible executions specified in Rule 971.1NY (b)(1)).

<sup>46</sup> See proposed Rule 971.1NY(c)(2)(C)(ii) (regarding “Unrelated quotes and orders”).

<sup>47</sup> See Rule 900.3NY(x) (defining a PNPB (or Post No Preference Blind) as a Limit Order that is to be executed in whole or in part on the Exchange, and the portion not so executed is to be ranked in the Consolidated Book, without routing any portion of the order to another Market Center; however, if the PNPB locks or crosses the NBBO, the price and size of the order is not disseminated. Once the PNPB no longer locks or crosses the NBBO, the price and size will be disseminated). See Rule 971.1NY(b) (providing that “[f]or purposes of determining whether a CUBE Order is eligible to initiate an Auction,” references to the NBBO or BBO “refer to the quoted market at the time the Auction is initiated”).

Auction.<sup>48</sup> Thus, the Exchange believes that the proposed change reflects current functionality and adds clarity, transparency and internal consistency to Exchange rules. Moreover, allowing unrelated quotes and orders resting in the Consolidated Book at the beginning of the Auction—including eligible PNPBs or the proposed RPNP/MMRPs—to interact with the CUBE Auction should increase the number of participants against which the CUBE Order may be executed, and is consistent with the primary goal of the CUBE Auction: To maximize price improvement opportunities for the CUBE Order.<sup>49</sup>

#### Early End Scenarios

The Exchange also proposes to modify Rule 971.1NY(c)(4), which specifies scenarios when a CUBE Auction would conclude early (*i.e.*, before the end of the RTI). The purpose of these provisions is to enable the CUBE Auction to integrate seamlessly within the Exchange’s Consolidated Book. Accordingly, a CUBE Auction will conclude early as a result of certain events that would otherwise disrupt the priority of the Auction within the Consolidated Book. Early conclusion allows the Exchange to appropriately handle unrelated quotes and orders without the CUBE Auction impacting that handling, and further allows the CUBE Order, which has been guaranteed an execution, to execute against the best-priced interest in the Auction.

Current Rule 971.1NY(c)(4)(B) provides that a CUBE Auction will conclude early if the Exchange receives during the RTI “an unrelated quote or order that is on the same side of the market as the CUBE Order, that is marketable against any RFR Responses or the NBBO (or the BBO, for a non-routable order) at the time of arrival.” Because PNP Orders, although non-routable are, by definition, checked against the NBBO (not the BBO), the Exchange proposes to modify the rule text to provide “or the BBO, for a non-routable order that is not a PNP

<sup>48</sup> See Rule 971.1NY(c)(5)(A) (providing that “[a]t each price level, any Customer orders resting on the Consolidated Book at the start of the CUBE Auction shall have first priority” to trade with the CUBE Order).

<sup>49</sup> The Exchange notes that to the extent that an order that was resting undisplayed at the start of the CUBE Order is eligible to trade with the CUBE Order, that interest would trade behind Customer and displayed interest, at a price, so as not to disturb the Exchange’s allocation rules, per proposed Rule 971.1NY(c)(5). Order Allocation (as discussed herein).

Order.”<sup>50</sup> The proposed language does not alter the current operation of this provision—as a same-side PNP Order that is marketable against the NBBO would cause an early end to the Auction—but merely clarifies that PNP Orders would differ because they would be checked against the NBBO, not the BBO. This carve out of PNP Order would include the proposed RPNP (and a PNPB). Also of note regarding this early end scenario is the modified definition of RFR Responses to include eligible interest resting in the Consolidated Book at the start of an Auction. This modified definition clarifies current functionality that an Auction may end early if incoming same-side interest is marketable against interest (*i.e.*, an RFR Response) that may not have been included in the NBBO or BBO but was resting undisplayed at the start of the Auction—which could include a proposed RPNP/MMRP or a PNPB. Thus, this provision, as modified, is consistent with CUBE functionality and simply updates the rule text to reflect the operation of PNP Orders and the interest that may cause an early end.

Current Rule 971.1NY(c)(4)(B) also provides that “[w]hen the Auction concludes, the CUBE Order will execute pursuant to paragraph (c)(5) [Order Allocation] of this Rule” and any unexecuted “GTX Orders” may trade with the interest that caused the Auction to end early and then will cancel. The Exchange proposes to modify this provision to make clear that any RFR Response—not just those marked as GTX Orders—are eligible to trade with the interest that caused the Auction to end. As proposed, “[a]ny RFR Responses that do not execute in the CUBE Auction will execute against the unrelated quote or order that caused the CUBE Auction to conclude early to the extent possible and GTX Orders will then cancel.”<sup>51</sup> This proposed change reflects the current operation of the

CUBE, thus adding clarity, transparency and internal consistency to Exchange rules, and accounts for the modified definition of RFR Responses (which also reflects current functionality) to include interest resting (potentially undisplayed) at the start of the Auction such as a PNPB or the proposed RPNP/MMRP.

Current Rule 971.1NY(c)(4)(C) provides that a CUBE Auction will conclude early if the Exchange receives during the RTI “any RFR Response that is marketable against the NBBO (or the BBO, for a non-routable order) at the time of arrival.” Consistent with the proposed change to paragraph (c)(4)(B) regarding same-side interest, the Exchange proposes to modify the text to make clear that incoming opposite-side interest is checked against “the BBO, for a non-routable order that is not a PNP Order,” as PNP Orders are checked against the NBBO.<sup>52</sup> As noted above, this proposed change [sic] not alter the current operation of this provision, but merely clarifies that distinct operation of (non-routable) PNP Orders. This carve out of PNP Order would include the proposed RPNP (and a PNPB).

In addition, the Exchange proposes to modify this provision to include opposite-side interest that is marketable against “any interest resting in the Consolidated Book.”<sup>53</sup> The Exchange notes that this proposed change reflects current functionality and clarifies that an RFR Response may be marketable against undisplayed interest in the Book—specifically a PNPB or a RPNP/MMRP—that is not included in the quoted BBO resulting in the early end of an Auction.<sup>54</sup> This proposed change reflects the current operation of the CUBE (in regards to a PNPB) and also updates the rule to reflect the proposed RPNP/MMRP, thus adding clarity, transparency and internal consistency to Exchange rules.

Current Rule 971.1NY(c)(4)(D) provides that a CUBE Auction will conclude early if the Exchange receives during the RTI “an unrelated, non-marketable quote or limit order that is

on the same side of the market as the CUBE Order to buy (sell) and that would adjust the lower (upper) bound of the range of permissible executions to be higher (lower) than the initiating price.”<sup>55</sup> To clarify existing functionality, the Exchange proposes to add new paragraph (c)(D)(i) to provide that a same-side IOC<sup>56</sup> that would otherwise meet the requirements of paragraph (c)(4)(D) (*i.e.*, if its limit price was incorporated into the NBBO, which it is not) would cause an Auction to end early, even if the IOC Order cancels without trading.<sup>57</sup> If such an IOC Order causes a CUBE Auction to end early, the CUBE Order and other eligible auction interest would be processed pursuant to paragraph (c)(4)(D). This proposed modification reflects existing functionality based on how the mechanism is built and would add clarity and transparency to the CUBE rule.

#### Order Allocation

The Exchange also proposes to modify Rule 971.1NY(c)(5) regarding the allocation of the CUBE Order with eligible interest. Current Rule 971.1NY(c)(5)(A) provides that, at each price level, the CUBE Order will first trade with resting Customer orders, followed by Customer orders that arrived during the Auction. Because a Customer may submit a PNPB or a RPNP—either of which may have an undisplayed price at which it is eligible to trade, the Exchange proposes to modify the Rule to make clear that only the “displayed” Customer interest benefits from Customer priority, pursuant to Rule 964NY(c)(2)(A).<sup>58</sup> This proposed change is consistent with the Exchange’s allocation rules,<sup>59</sup> current CUBE operation and simply updates the rule to reflect the treatment of PNPB and the proposed RPNP.

As noted above, the Initiating Participant may guarantee the execution

<sup>50</sup> See proposed Rule 971.1NY(c)(4)(B) (“*Same Side Marketable Against RFR Responses or NBBO (or BBO)*”) (providing, in relevant part, that the Auction would end early if during the RTI the Exchange receives a same-side unrelated quote or order that is marketable against “any RFR Responses or the NBBO (or the BBO, for a non-routable order that is not a PNP Order) at the time of arrival”).

<sup>51</sup> See *id.* Consistent with this change, the Exchange also proposes to modify paragraph (c)(4)(D), another early end scenario based on same-side interest with similar rule text, to replace “GTX Orders” with “RFR Responses” in terms of interest received during the RTI that may trade in the Auction after the CUBE Order is filled. See proposed Rule 971.1NY(c)(4)(D) (providing, in relevant part, that “[u]nfilled RFR Responses are eligible to execute against the unrelated interest that caused the CUBE Auction to conclude early and GTX Orders will then cancel”).

<sup>52</sup> See proposed Rule 971.1NY(c)(4)(C).

<sup>53</sup> See proposed Rule 971.1NY(c)(4)(C) (*Opposite Side Marketable Against Interest in the Consolidated Book, the NBBO (or BBO) at the Time of Arrival*) (providing, in relevant part, that the Auction would end early if during the RTI the Exchange receives an “any RFR Response that is marketable against the any interest resting in the Consolidated Book, the NBBO (or the BBO, for a non-routable order that is not a PNP Order) at the time of arrival”).

<sup>54</sup> See *supra* note 47 (regarding Rule 971.1NY(b), providing that “[f]or purposes of determining whether a CUBE Order is eligible to initiate an Auction,” references to the NBBO or BBO “refer to the quoted market at the time the Auction is initiated”).

<sup>55</sup> See *supra* note 51 (regarding modifications to last sentence of paragraph (c)(5)(D) regarding unfilled RFR Responses and GTX Orders).

<sup>56</sup> See *supra* note 8 (defining IOC Order).

<sup>57</sup> See proposed Rule 971.1NY(c)(4)(D)(i).

<sup>58</sup> See proposed Rule 971.1NY(c)(5)(A) (providing that, at each price level, displayed Customer interest on the Book at the start of the Auction have first priority, followed by displayed Customer orders that arrived as RFR Responses, pursuant to Rule 964NY(c)(2)(A), provides that an inbound order will first be matched against all available displayed Customer interest in the Book (emphasis added). See also proposed Rule 971.1NY(c)(5)(B) (providing that “[a]fter displayed Customer interest at a particular price level has been satisfied, remaining contracts shall be allocated among the Contra Order and RFR Responses as follows:”).

<sup>59</sup> See Rule 964NY(c)(2)(A) (“the inbound order will first be matched against all available displayed Customer interest in the Consolidated Book”).

of the CUBE via a single stop price, a range of prices up/down to match the best-priced RFR Responses (assuming size of CUBE Order remains) or a range of prices matching the best-priced RFR Responses up/down to an auto-match limit price. The Exchange proposes to modify the rules regarding CUBE Order allocation in these scenarios to clarify current functionality regarding the treatment of a PNPB and to account for the proposed RPNP and MMRP, which as RFR Responses, may be eligible to trade in the Auction even if undisplayed. The current CUBE Order allocation rule does not address the priority of RFR Responses that are not displayed.

First, the Exchange proposes to modify the Rule regarding the allocation of a CUBE Order that is guaranteed by a single stop price. In short, the current rule provides that the CUBE Order will trade with any RFR Responses priced better than the stop price (by size pro rata), starting with the best-priced RFR Responses until the stop price is reached, at which price the Contra Order is entitled to its allocation guarantee.<sup>60</sup> Regarding the priority of RFR Responses priced better than the stop price, the Exchange proposes to modify the rule to provide that “[a]t each price point, the CUBE Order shall be allocated first to GTX Orders and displayed RFR Responses pursuant to the size pro rata algorithm set forth in Rule 964NY(b)(3), and next to any undisplayed RFR Responses at that price in time priority, pursuant to Rule 964NY(c).”<sup>61</sup> The Exchange also proposes to modify the Rule to specify the priority of RFR Responses at the stop price (if any portion of the CUBE Order remains after the Contra Order receives its allocation guarantee).<sup>62</sup> The modified rule would provide that “[a]ny remaining CUBE Order contracts at the stop price shall be allocated first among remaining GTX Orders and displayed RFR Responses pursuant to the size pro rata algorithm set forth in Rule 964NY(b)(3), and next to any undisplayed RFR Responses pursuant to Rule 964NY(c).”<sup>63</sup> This proposed change is consistent with the Rule 964NY and simply updates the rule to reflect current functionality regarding the treatment of a PNPB and to account for the proposed RPNP/MMRP.

Second (and consistent with the changes to CUBE Orders guaranteed by a stop price), the Exchange proposes to

modify the Rule regarding the allocation of a CUBE Order that is guaranteed by auto match. In short, the current rule provides that the Contra Order is “allocated an equal number of contracts as the aggregate size of all other RFR Responses at each price level” starting with the best priced RFR Response, “until a price point is reached where the balance of the CUBE Order can be fully executed (the ‘clean-up price’).”<sup>64</sup> At the clean-up price, if the Contra Order has not yet received its allocation guarantee, and if sufficient size of the CUBE Order remains, the Contra Order will be allocated the requisite additional contracts.<sup>65</sup> Further, under the current rule, “[i]f there are other RFR Responses at the clean-up price, the remaining CUBE Order contracts will be allocated to such interest pursuant to the size pro rata algorithm set forth in Rule 964NY(b)(3).”<sup>66</sup> The Exchange proposes to modify the rule to specify the priority of Responses at the clean-up price (if any portion of the CUBE Order remains after the Contra Order receives its allocation guarantee) to provide that CUBE Order contracts “will be allocated first to GTX Orders and displayed RFR Responses pursuant to the size pro rata algorithm set forth in Rule 964NY(b)(3), and next to any undisplayed RFR Responses at that price in time priority, pursuant to Rule 964NY(c).”<sup>67</sup> This proposed change is consistent with the operation of Rule 964NY and simply updates the rule to reflect current functionality regarding the treatment of a PNPB and to account for the proposed RPNP/MMRP.

Finally, in a similar vein, the Exchange proposes to modify the rule to address how the CUBE Order will be allocated when auto-match limit is selected. In short, the current rule provides that the CUBE Order will trade with any RFR Responses priced better than the auto-match limit price (size pro rata), starting with the best-priced Responses until the auto-match limit price is reached.<sup>68</sup> At prices equal to or worse than the auto-match limit price (assuming sufficient size of CUBE Order remains), the Contra Order will be allocated an equal number of contracts as the aggregate size of all other RFR Responses and will receive its allocation

guarantee (if not already met) at the clean-up price. If CUBE Order contracts remain after the Contra Order gets its allocation guarantee, RFR Responses will trade with the CUBE Order at that (clean-up) price, pro rata.<sup>69</sup> The Exchange proposes to modify paragraph (c)(5)(B)(iii)(a), regarding the allocation of the CUBE Order with the best-priced Responses, to provide that “[a]t each price point, the CUBE Order shall be allocated first to GTX Orders and displayed RFR Responses pursuant to the size pro rata algorithm set forth in Rule 964NY(b)(3), and next to any undisplayed RFR Responses at that price in time priority, pursuant to Rule 964NY(c).”<sup>70</sup> Regarding the CUBE Order trading with RFR Responses at the clean-up price (if size remains), the Exchange proposes to modify the rule to provide such contracts “will be allocated first to GTX Orders and displayed RFR Responses pursuant to the size pro rata algorithm set forth in Rule 964NY(b)(3), and next to any undisplayed RFR Responses at that price in time priority, pursuant to Rule 964NY(c).”<sup>71</sup> This proposed change is consistent with the operation of the CUBE and simply updates the rule to reflect current functionality regarding the treatment of a PNPB and to account for the proposed RPNP/MMRP.

The following is an example that illustrates RPNPs trading in a CUBE Auction at their undisplayed price in time priority (behind displayed interest).

CUBE Example (the MPV is \$0.01)

BOX 100 × 1.00 – 1.25 × 100

MM 10 × 0.95 – 1.30 × 10

Firm1 RPNP B 100 @1.26

Firm2 RPNP B 100 @1.26

CUBE Order S 100 @1.20/Contra Order

Buy guaranteed by automatch

Expected Result

BOX NBO @1.25

Firm1 bid reprices and is eligible to trade 100 @1.25 and will display @ 1.24 (priced back one MPV from the NBO)

Firm2 bid reprices and is eligible to trade 100 @1.25 and will display @ 1.24 (priced back one MPV from the NBO)

At the end of the CUBE auction: The CUBE Order sells 40 to the Contra Order @1.25 (*i.e.*, 40% participation guarantee), per Rule 971.1NY(c)(5)(B)(ii)(a), then 60 to

<sup>64</sup> See Rule 971.1NY(c)(5)(B)(ii)(a).

<sup>65</sup> See Rule 971.1NY(c)(5)(B)(ii)(b).

<sup>66</sup> See *id.* As is the case today, if all RFR Responses are filled, any remaining portion of CUBE Order contracts is allocated to the Contra Order at the initiating price and, in the event there are no RFR Responses received in a given Auction, the CUBE Order trades entirely with the Contra Order at the initiating price. See Rule 971.1NY(c)(5)(B)(ii)(b),(c).

<sup>67</sup> See proposed Rule 971.1NY(c)(5)(B)(ii)(b).

<sup>68</sup> See Rule 971.1NY(c)(5)(B)(iii)(a).

<sup>69</sup> See Rule 971.1NY(c)(5)(B)(iii)(b).

<sup>70</sup> See proposed Rule 971.1NY(c)(5)(B)(iii)(a).

<sup>71</sup> See proposed Rule 971.1NY(c)(5)(B)(iii)(b).

<sup>60</sup> See Rule 971.1NY(c)(5)(B)(i). Rule 964NY(b)(2) sets forth priority and order allocation.

<sup>61</sup> See proposed Rule 971.1NY(c)(5)(B)(i)(a).

<sup>62</sup> See proposed Rule 971.1NY(c)(5)(B)(i)(b).

<sup>63</sup> See *id.*

Firm1 @1.25, per Rule  
971.1NY(c)(5)(B)(ii)(b))

\* \* \* \* \*

## Implementation

The Exchange will announce by Trader Update the implementation date of the proposed rule change within 90 days of the effective date of this rule filing.

## 2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>72</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act,<sup>73</sup> in particular, in that it is 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.

## RPNP and MMRP

The proposed RPNP would remove impediments to and perfect the mechanism of a free and open market and a national market system because RPNPs would provide market participants with greater flexibility and control over how their orders interact with liquidity on the Exchange. The Exchange believes this proposal allows market participants to provide and access greater liquidity on the Exchange, thus benefiting Exchange members. The proposed order type would provide a means to display such orders at prices that are designed to maximize their opportunities for execution. Specifically, allowing any eligible RPNP to be repriced and potentially trade at multiple price points would improve the mechanism of price discovery. The Exchange believes that ranking a repriced RPNP with other interest eligible to trade at a price respects and preserves principles of Customer, as well as price-time, priority and therefore would promote just and equitable principles of trade. The Exchange notes that the RPNP is materially the same as the RPNP order type recently approved for trading on NYSE Arca, except as noted herein.<sup>74</sup>

Similar to the proposed RPNP, the proposed MMRP quote designation would remove impediments to and perfect the mechanism of a free and open market and a national market

system because MMRPs would provide Market Makers with increased control over interactions with contra-side liquidity and would increase opportunities for such interactions. The Exchange notes that, absent the proposed repricing functionality associated with the MMRP, a Market Maker quote that locks or crosses interest on the Exchange or an away market would reject or cancel. In the case of MMRPs, the proposal would afford Market Makers more certainty when providing liquidity, while ensuring that MMRPs priced too far through the contra-side NBBO would cancel or reject after trading with any eligible interest on the Exchange. The Exchange notes that the proposed MMRP is optional and Market Makers have the choice to utilize this quote type (or not). The Exchange believes that ranking the repriced MMRP with other interest available to trade at a price respects and preserves principles of Customer, as well as price-time, priority and therefore would remove impediments to and perfect the mechanism of a free and open market and a national market system.

Because the options market is quote driven and Market Makers are vital to the price discovery process, the Exchange believes that the proposed (optional) quote types would provide Market Makers with a greater level of determinism, in terms of managing their exposure, and thus may encourage more aggressive liquidity provision, resulting in more trading opportunities and tighter spreads. This too would help improve the mechanism of price discovery. Accordingly, the Exchange believes that the proposal would improve overall market quality and enhance competition on the Exchange to the benefit of all market participants.

Moreover, the Exchange also notes that the proposed MMRP is materially the same as the MMRP quote designation recently approved for trading on NYSE Arca, except as noted herein.<sup>75</sup> Accordingly, the Exchange believes that the proposal would improve overall market quality and improve competition on the Exchange, to the benefit of all market participants.

## RPNP/MMRP and the CUBE Auction

The Exchange believes that the proposed changes to the conduct of the CUBE Auction would remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed changes are consistent with the current operation of the CUBE

and would avoid disturbing priority in the Consolidated Book, in accordance with Rule 964NY, regarding priority of quotes and orders.

Specifically, the proposal to modify rule text to make clear that RFR Responses include interest resting in the Consolidated Book at the start of the Auction would align the rule text with current functionality and add transparency and internal consistency to Exchange rules, which in turn, would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system. This proposed change aligns with the treatment of Customer interest resting at the start of a CUBE Auction<sup>76</sup> and would make clear that the proposed RPNP/MMRP (and PNPBs) may participate in the Auction even if resting undisplayed on the Book at the start of a CUBE Auction (and not included in the quoted market).<sup>77</sup> The Exchange believes that allowing eligible unrelated quotes and orders resting on the Consolidated Book at the start of an Auction—including eligible RPNP/MMRPs (and PNPBs)—to interact with the CUBE Auction protects investors and the public interest because this inclusion of resting interest in the Auction should increase the number of participants against which the CUBE Order may be executed, and is consistent with the primary goal of the CUBE Auction: To maximize price improvement opportunities for the CUBE Order, while seamlessly interacting with the Consolidated Book.<sup>78</sup> Similarly, the proposed modifications to make clear that—in the event of an early end to the Auction—all RFR Responses, not solely GTX Orders, are eligible to trade with interest received in the Auction, which would protect investors and the investing public because it adds clarity, specificity, and transparency to Exchange rules.

Further, the proposed modification of the early end scenarios would remove

<sup>76</sup> See Rule 971.1NY(c)(5)(A) (providing that “[a]t each price level, any Customer orders resting on the Consolidated Book at the start of the CUBE Auction shall have first priority” to trade with the CUBE Order).

<sup>77</sup> See Rule 971.1NY(b) (providing that “[f]or purposes of determining whether a CUBE Order is eligible to initiate an Auction,” references to the NBBO or BBO “refer to the quoted market at the time the Auction is initiated”).

<sup>78</sup> The Exchange notes that to the extent that an order that was resting undisplayed at the start of the CUBE Order is eligible to trade with the CUBE Order, that interest would trade behind Customer and displayed interest, at a price, so as not to disturb the Exchange’s allocation model, per proposed Rule 971.1NY(c)(5), Order Allocation (as discussed herein).

<sup>72</sup> 15 U.S.C. 78f(b).

<sup>73</sup> 15 U.S.C. 78f(b)(5).

<sup>74</sup> See NYSE Arca Repricing Approval Order, *supra* note 4. See also *supra* note 6 (regarding the Exchange’s Customer and price-time priority scheme).

<sup>75</sup> *Id.*

impediments to and perfect the mechanisms of a free and open market and a national market system because the changes would align the rule text with existing functionality and would provide clarity and transparency in Exchange rules of when a CUBE Auction would conclude early. As noted above, the rationale for an early conclusion to an Auction is to allow the Exchange to appropriately handle unrelated quotes and orders without the CUBE Auction impacting that handling, and further allow a CUBE Order, which has been guaranteed an execution, to execute against the Contra Order and any RFR. The changes to the early end provisions are designed to ensure internal consistency (in regards to the proposed modified definition of RFR Responses) as well as clarify current functionality of the early end checks (to carve out PNP Orders from BBO check and to make clear that incoming interest may be checked for marketability against interest in the Consolidated Book, not just the BBO) to appropriately account for the fact that the best-priced interest in the Book may not be displayed and thus not included in the quoted BBO (such as the proposed RPNP/MMRP). Thus, the Exchange believes that the proposed changes are therefore consistent with the protection of investors and the public interest because the changes provide specificity in Exchange rules regarding when an Auction would conclude early.

In addition, the proposal to specify that IOC Orders that arrive during an Auction may cause the Auction to end early would promote just and equitable principles of trade and benefit investors as this clarification regarding how the CUBE Auction mechanism operates ensures that investors are aware of the potential impact of IOC Orders (even ones that do not trade) on an Auction in progress.

Finally, the proposal to clarify the order allocation provision would promote just and equitable principles of trade and benefit investors as this clarification would make clear that the priority of RFR Responses is consistent with the Exchange Customer and price-time priority model and would afford first priority, at each price point, to displayed RFR Responses followed by undisplayed RFR Responses. These proposed changes are consistent with the current operation of the CUBE and would avoid disturbing priority in the Consolidated Book, in accordance with Rule 964NY, regarding priority of quotes and orders.

#### Technical Changes

The Exchange notes that the proposed organizational and non-substantive changes to the rule text would provide clarity and transparency to Exchange rules and would promote just and equitable principles of trade and remove impediments to, and perfect the mechanism of, a free and open market and a national market system.<sup>79</sup> The proposed rule amendments would also provide internal consistency within Exchange rules and operate to protect investors and the investing public by making the Exchange rules easier to navigate and comprehend.

#### *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 Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. The Exchange believes the proposed rule change is procompetitive because it would enable the Exchange to provide market participants with functionality that is similar to that of other options exchanges.<sup>80</sup>

The Exchange believes the proposed MMRP would add value to market making on the Exchange and the proposed RPNP would provide market participants the option of exercising greater control over how orders interact with contra-side liquidity both on the Exchange and on away markets. The proposed MMRP/RPNP would allow market participants to exert greater control over how their quotes and orders interact with liquidity on the Exchange, thereby attracting more investors to the Exchange, which, in turn, leads to greater price discovery and improves overall market quality.

The Exchange does not believe the proposal would impose a burden on competition among the options exchanges but instead, because the Exchange would be offering the proposed (optional) MMRP and RPNP, the proposal would add to the existing competitive landscape. In this highly competitive market, the Exchange would be at a competitive disadvantage absent this proposal, which adopts functionality available on other options exchanges. Permitting the Exchange to operate on an even playing field relative

to other exchanges that have similar functionality removes impediments to and perfects the mechanism for a free and open market and a national market system. The proposal does not impose an undue burden on intramarket competition because the proposed MMRP would be available to all Market Makers on the Exchange and the proposed RPNP would be available to all market participants. The proposal is structured to offer the same enhancement to all Market Makers and/or market participants, regardless of size, and would not impose a competitive burden on any participant.

The proposed MMRP, which provide Market Makers with enhanced determinism over their quotes, may contribute to more aggressive quoting by Market Makers, resulting in more trading opportunities and tighter spreads. To the extent this purpose is achieved, the proposed MMRP would enhance the market making function on the Exchange, which would improve overall market quality and improve competition on the Exchange to the benefit of all market participants.

The Exchange likewise does not believe that the proposed clarifications to the rule text regarding the CUBE Auction would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The rule changes are not intended to address any competitive issues. Rather, the Exchange is proposing to add more specificity, clarity and transparency regarding the current operation of the CUBE Auction, particularly in light of the proposed MMRP/RPNP.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

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

<sup>79</sup> See, e.g., *supra* notes 7, 19, 20, 28.

<sup>80</sup> See NYSE Arca Repricing Approval Order, *supra* note 4.

19(b)(3)(A) of the Act<sup>81</sup> and Rule 19b-4(f)(6) thereunder.<sup>82</sup>

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act<sup>83</sup> normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)<sup>84</sup> permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. As noted above, the proposed order type and quote designation are substantially identical to those utilized on NYSE Arca, Inc., and the differences noted herein do not raise substantive or novel issues. Waiver of the operative delay would allow the Exchange to immediately implement the proposed functionality in coordination with the availability of the technology supporting the proposal, which is anticipated to be less than 30 days after the filing of the proposed rule change. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.<sup>85</sup>

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](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEAMER-2019-06 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-NYSEAMER-2019-06. 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-NYSEAMER-2019-06 and should be submitted on or before April 23, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>86</sup>

**Eduardo A. Aleman,**

*Deputy Secretary.*

[FR Doc. 2019-06308 Filed 4-1-19; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85431; File No. SR-NASDAQ-2019-019]

### Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay Implementation of the Midpoint Trade Now Functionality

March 27, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on March 19, 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 delay implementation of the Midpoint Trade Now functionality until Q2 2019.

#### 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.

<sup>86</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>81</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>82</sup> 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.

<sup>83</sup> 17 CFR 240.19b-4(f)(6).

<sup>84</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>85</sup> 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).

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

On November 9, 2019 [sic], the Exchange filed a proposed rule change to establish a new Midpoint Trade Now Order Attribute, which will allow a resting Order that becomes locked at its non-displayed price by an incoming Midpoint Peg Post-Only Order to automatically execute against crossing or locking interest, including potentially against the Midpoint Peg Post-Only Order that locked the resting Order, as a liquidity taker.<sup>3</sup> The proposed rule change indicated that the Exchange would begin implementing Midpoint Trade Now in Q1 2019.<sup>4</sup> The Exchange proposes to delay the implementation of Midpoint Trade Now functionality until Q2 2019. The Exchange will issue an Equity Trader Alert notifying participants prior to implementing the functionality. The Exchange proposes this delay to allow the Exchange further time to implement this functionality.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,<sup>5</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act,<sup>6</sup> in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by allowing the Exchange additional time to implement the Midpoint Trade Now functionality.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposal to delay the adoption of the Midpoint Trade Now functionality does not impose an undue burden on competition. Delaying Midpoint Trade Now will simply allow the Exchange additional time to implement this functionality.

<sup>3</sup> See Securities Exchange Act Release No. 84621 (Nov. 19, 2018), 83 FR 60514 (Nov. 26, 2018) (SR-NASDAQ-2018-090).

<sup>4</sup> See *id.*

<sup>5</sup> 15 U.S.C. 78f(b).

<sup>6</sup> 15 U.S.C. 78f(b)(5).

*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<sup>7</sup> and Rule 19b-4(f)(6) thereunder.<sup>8</sup>

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act<sup>9</sup> normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)<sup>10</sup> 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 can provide prior notice of the implementation delay before the end of Q1 2019. For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.<sup>11</sup>

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

<sup>7</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>8</sup> 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 Commission has waived this requirement in this case.

<sup>9</sup> 17 CFR 240.19b-4(f)(6).

<sup>10</sup> 17 CFR 240.19b-4(f)(6)(iii).

<sup>11</sup> 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).

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](mailto:rule-comments@sec.gov). Please include File Number SR-NASDAQ-2019-019 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-NASDAQ-2019-019. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2019-019 and should be submitted on or before April 23, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>12</sup>

**Eduardo A. Aleman,**

*Deputy Secretary.*

[FR Doc. 2019-06309 Filed 4-1-19; 8:45 am]

**BILLING CODE 8011-01-P**

## SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA-2019-0011]

### Public Availability of Social Security Administration Fiscal Year (FY) 2017 Service Contract Inventory

**AGENCY:** Social Security Administration.

**ACTION:** Notice of public availability of FY 2017 service contract inventories.

**SUMMARY:** In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010, we are publishing this notice to advise the public of the availability of the FY 2017 Service Contract inventory. This inventory provides information on FY 2017 service contract actions over \$25,000. We organized the information by function to show how we distribute contracted resources throughout the agency. We developed the inventory in accordance with guidance issued on December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at <https://obamawhitehouse.archives.gov/sites/default/files/omb/procurement/memo/service-contract-inventory-guidance.pdf>. You can access the inventory and summary of the inventory on our homepage at the following link: <http://www.socialsecurity.gov/sci>.

**FOR FURTHER INFORMATION CONTACT:** Ronnetta Mason, Office of Budget, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401. Phone (410) 597-1955, email [Ronnetta.Mason@ssa.gov](mailto:Ronnetta.Mason@ssa.gov).

**Michelle King,**

*Deputy Commissioner for Budget, Finance, and Management.*

[FR Doc. 2019-06338 Filed 4-1-19; 8:45 am]

**BILLING CODE 4191-02-P**

## SUSQUEHANNA RIVER BASIN COMMISSION

### Projects Rescinded for Consumptive Uses of Water

**AGENCY:** Susquehanna River Basin Commission.

**ACTION:** Notice.

**SUMMARY:** This notice lists the approved by rule projects rescinded by the Susquehanna River Basin Commission during the period set forth in **DATES**.

**DATES:** February 1-28, 2019.

**ADDRESSES:** Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110-1788.

**FOR FURTHER INFORMATION CONTACT:**

Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238-0423, ext. 1312; fax: (717) 238-2436; email: [joyler@srbc.net](mailto:joyler@srbc.net). Regular mail inquiries may be sent to the above address. See also Commission website at [www.srbc.net](http://www.srbc.net).

**SUPPLEMENTARY INFORMATION:** This notice lists the projects, described below, being rescinded for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

#### Rescinded ABR Issued:

Chief Oil & Gas, LLC; Pad ID: HEMLOCK RIDGE ESTATES UNIT PAD, ABR-201810003; McNett Township, Lycoming County, Pa.; Rescinded Date: February 26, 2019.

**Authority:** Pub. L. 91-575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: March 27, 2019.

**Jason E. Oyler,**

*General Counsel and Secretary to the Commission.*

[FR Doc. 2019-06288 Filed 4-1-19; 8:45 am]

**BILLING CODE 7040-01-P**

## SUSQUEHANNA RIVER BASIN COMMISSION

### Projects Approved for Consumptive Uses of Water

**AGENCY:** Susquehanna River Basin Commission.

**ACTION:** Notice.

**SUMMARY:** This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

**DATES:** February 1-28, 2019.

**ADDRESSES:** Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110-1788.

**FOR FURTHER INFORMATION CONTACT:**

Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238-0423, ext. 1312; fax: (717) 238-2436; email: [joyler@srbc.net](mailto:joyler@srbc.net). Regular mail inquiries may be sent to the above address.

**SUPPLEMENTARY INFORMATION:** This notice lists the projects, described below, receiving approval for the

consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(e) and 806.22 (f) for the time period specified above:

#### Approvals By Rule Issued Under 18 CFR 806.22(f):

1. Seneca Resources Company, LLC; Pad ID: Rich Valley Pad G, ABR-201402001.R1; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 4, 2019.

2. Seneca Resources Company, LLC; Pad ID: Rich Valley Pad F, ABR-201402002.R1; Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: February 4, 2019.

3. Repsol Oil & Gas USA, LLC; Pad ID: KROPIEWNICKI (07 038) J, ABR-201902004.R1; Apolacon Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 11, 2019.

4. Repsol Oil & Gas USA, LLC; Pad ID: YORK (07 088) R, ABR-201402005.R1; Little Meadows Borough and Apolacon Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 11, 2019.

5. Range Resources—Appalachia, LLC; Pad ID: Cornwall 1H-5H, ABR-201402006.R1; Lewis Township, Lycoming County, Pa.; Consumptive Use of Up to 2.0000 mgd; Approval Date: February 11, 2019.

6. Repsol Oil & Gas USA, LLC; Pad ID: COREY (07 089) J, ABR-201402008.R1; Choconut Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 11, 2019.

7. Repsol Oil & Gas USA, LLC; Pad ID: CAPRIO (07 077) S, ABR-201402011.R1; Apolacon Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: February 14, 2019.

8. SWN Production Company, LLC; Pad ID: RU-65-LEONARD-PAD; ABR-201402010.R1; Jackson Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: February 15, 2019.

9. Cabot Oil & Gas Corporation; Pad ID: MakoskyT P1, ABR-201402012.R1; Brooklyn Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: February 25, 2019.

10. Cabot Oil & Gas Corporation; Pad ID: MillardK P1, ABR-201402013.R1; Jessup Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: February 25, 2019.

11. Chief Oil & Gas, LLC; Pad ID: HEMLOCK RIDGE ESTATES PAD,

<sup>12</sup> 17 CFR 200.30-3(a)(12).

ABR–201902003; McNett Township, Lycoming County, Pa.; Consumptive Use of Up to 2.5000 mgd; Approval Date: February 25, 2019.

**Authority:** Pub. L. 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: March 27, 2019.

**Jason E. Oyler,**

*General Counsel and Secretary to the Commission.*

[FR Doc. 2019–06290 Filed 4–1–19; 8:45 am]

**BILLING CODE 7040–01–P**

## SUSQUEHANNA RIVER BASIN COMMISSION

### Actions Taken at March 15, 2019, Meeting

**AGENCY:** Susquehanna River Basin Commission.

**ACTION:** Notice.

**SUMMARY:** As part of its regular business meeting held on March 15, 2019, in Annapolis, Maryland, the Commission approved the applications of certain water resources projects, and took additional actions, as set forth in the **SUPPLEMENTARY INFORMATION** below.

**DATES:** March 15, 2019.

**ADDRESSES:** Susquehanna River Basin Commission, 4423 N. Front Street, Harrisburg, PA 17110–1788.

**FOR FURTHER INFORMATION CONTACT:** Jason E. Oyler, General Counsel and Secretary, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: [joyler@srbc.net](mailto:joyler@srbc.net). Regular mail inquiries may be sent to the above address. See also Commission website at [www.srbc.net](http://www.srbc.net).

**SUPPLEMENTARY INFORMATION:** In addition to the actions taken on projects identified in the summary above and the listings below, the following items were also presented or acted upon at the business meeting: (1) Adopting a final FY2020 budget; (2) approval of several contracts, grant amendments and agreements; (3) adopting a resolution authorizing amendments to the retiree health trust; (4) authorized the executive director to prepare a final letter in response to the 2017 Pennsylvania performance audit; and (5) approved extension of an emergency certificate issued to Knouse Foods Cooperative, Inc.

### Adoption of Resolution 2019–04

The Commission adopted Resolution 2019–04 authorizing the balancing of Approvals by Rule under 18 CFR 806.22(f) (ABR(f)) renewal cycle workload. The number of ABR(f)

renewals required to be submitted varies greatly each year, with a maximum year of 620 renewals and a minimum year of 190 renewals, which places a difficult administrative burden on the Commission to review the renewals in a timely manner in heavy years and/or would require an increase in costs associated with temporary staffing of the ABR(f) program.

To resolve the imbalance, the Commission, pursuant to 18 CFR 806.8, waived the strict application of 18 CFR 806.22(f)(10) to up to 601 ABR(f) approvals and authorized the Executive Director to add one or two years to the term of those approvals to best balance the projected workload over the five year renewal cycle. The list of extended approvals are published on the Commission's website at <https://www.srbc.net/our-work/public-reference-manual/docs/abrf-term-adjustment-list.pdf>.

### Project Applications Approved

The Commission approved the following project applications:

1. Project Sponsor and Facility: ADLIB Resources, Inc. (Meshoppen Creek), Springville Township, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 0.499 mgd (peak day) (Docket No. 20150301).

2. Project Sponsor: Aqua Pennsylvania, Inc. Project Facility: Beech Mountain System, Butler Township, Luzerne County, Pa. Application for groundwater withdrawal of up to 0.144 mgd (30-day average) from Beech Mountain Well 1.

3. Project Sponsor: Aqua Pennsylvania, Inc. Project Facility: Beech Mountain System, Butler Township, Luzerne County, Pa. Application for groundwater withdrawal of up to 0.144 mgd (30-day average) from Beech Mountain Well 2.

4. Project Sponsor: Aqua Pennsylvania, Inc. Project Facility: Beech Mountain System, Butler Township, Luzerne County, Pa. Application for groundwater withdrawal of up to 0.124 mgd (30-day average) from Beech Mountain Well 3.

5. Project Sponsor and Facility: Chesapeake Appalachia, L.L.C. (Susquehanna River), Braintrim Township, Wyoming County, Pa. Application for renewal of surface water withdrawal of up to 3.000 mgd (peak day) (Docket No. 20150303).

6. Project Sponsor: Corning Incorporated. Project Facility: Corning Innovation Support Center, Town of Big Flats, Chemung County, N.Y. Application for groundwater

withdrawal of up to 0.540 mgd (30-day average) from Carpenter Road Well 1.

7. Project Sponsor: Corning Incorporated. Project Facility: Corning Innovation Support Center, Town of Big Flats, Chemung County, N.Y. Application for groundwater withdrawal of up to 0.540 mgd (30-day average) from Carpenter Road Well 2.

8. Project Sponsor and Facility: Farmers Pride, Inc., Bethel Township, Lebanon County, Pa. Application for renewal of groundwater withdrawal of up to 0.060 mgd (30-day average) from Well 1 (Docket No. 19881101).

9. Project Sponsor and Facility: Linde Corporation (Lackawanna River), Fell Township, Lackawanna County, Pa. Application for renewal of surface water withdrawal of up to 0.905 mgd (peak day) (Docket No. 20150307).

10. Project Sponsor and Facility: Shadow Ranch Resort, Inc. (Tunkhannock Creek), Tunkhannock Township, Wyoming County, Pa. Application for renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20150309).

11. Project Sponsor and Facility: State College Borough Water Authority, Ferguson Township, Centre County, Pa. Application for renewal of groundwater withdrawal of up to 0.490 mgd (30-day average) from Well 57 (Docket No. 19890504).

12. Project Sponsor: SUEZ Water Pennsylvania Inc. Project Facility: Center Square Operation, Upper Allen Township, Cumberland County, Pa. Application for groundwater withdrawal of up to 0.107 mgd (30-day average) from Well 1.

13. Project Sponsor: SUEZ Water Pennsylvania Inc. Project Facility: Center Square Operation, Upper Allen Township, Cumberland County, Pa. Application for renewal of groundwater withdrawal of up to 0.379 mgd (30-day average) from Well 2 (Docket No. 19861104).

14. Project Sponsor and Facility: Sugar Hollow Water Services LLC (Martins Creek), Hop Bottom Borough, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 0.360 mgd (peak day) (Docket No. 20150304).

15. Project Sponsor and Facility: SWEPI LP (Cowanessque River), Westfield Township, Tioga County, Pa. Application for renewal of surface water withdrawal of up to 0.375 mgd (peak day) (Docket No. 20150311).

16. Project Sponsor and Facility: SWN Production Company, LLC (Martins Creek), Brooklyn Township, Susquehanna County, Pa. Application for renewal of surface water withdrawal

of up to 0.997 mgd (peak day) (Docket No. 20150310).

17. Project Sponsor and Facility: Village of Windsor, Broome County, N.Y. Application for groundwater withdrawal of up to 0.380 mgd (30-day average) from Well 1.

18. Project Sponsor and Facility: Village of Windsor, Broome County, N.Y. Application for groundwater withdrawal of up to 0.380 mgd (30-day average) from Well 2.

### Commission-Initiated Project Approval Modifications

1. Project Sponsor and Facility: East Donegal Township Municipal Authority, East Donegal Township, Lancaster County, Pa. Conforming the grandfathering amount with the forthcoming determination for a withdrawal of up to 0.351 mgd (30-day average) from Glatfelter Springs (Docket No. 20110305).

2. Project Sponsor and Facility: Hanover Country Club, Abbottstown Borough, Adams County, Pa. Conforming the grandfathering amount with the forthcoming determination for a groundwater withdrawal of up to 0.122 mgd (30-day average) from Well 1 and up to 0.108 mgd (30-day average) from Well 2 (Docket No. 20020828).

3. Project Sponsor and Facility: Mars Wrigley Confectionery US, LLC, Elizabethtown Borough, Lancaster County, Pa. Conforming the grandfathering amount with the forthcoming determination for groundwater withdrawal of up to 0.112 mgd (30-day average) from Well 6 (Docket No. 20010804).

**Authority:** Pub. L. 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: March 27, 2019.

**Jason E. Oyler,**

*General Counsel and Secretary to the Commission.*

[FR Doc. 2019–06289 Filed 4–1–19; 8:45 am]

**BILLING CODE 7040–01–P**

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### Notice of Final Federal Agency Actions on Proposed Highway in Utah

**AGENCY:** Utah Department of Transportation (UDOT), Federal Highway Administration (FHWA), Department of Transportation.

**ACTION:** Notice of Limitation on Claims for Judicial Review of Actions Taken by UDOT on behalf of FHWA.

**SUMMARY:** This notice announces certain actions taken by UDOT that are final

Federal agency actions. These actions relate to Purgatory Road, a proposed highway project between State Route (SR) 9 and Southern Parkway (SR 7), in the County of Washington, State of Utah. Those actions grant licenses, permits and/or approvals for the project.

**DATES:** By this notice, the FHWA, on behalf of UDOT, is advising the public of final Federal 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 August 30, 2019. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

**FOR FURTHER INFORMATION CONTACT:** Naomi Kisen, Environmental Program Manager, UDOT Environmental Services, P.O. Box 143600, Salt Lake City, UT 84114; telephone: (801) 965–4005; email: [nkisen@utah.gov](mailto:nkisen@utah.gov). UDOT's normal business hours are 8:00 a.m. to 5:00 p.m. (Mountain Time Zone), Monday through Friday, except State and Federal holidays.

**SUPPLEMENTARY INFORMATION:** Effective January 17, 2017, FHWA assigned to UDOT certain responsibilities of FHWA for environmental review, consultation, and other actions required by applicable Federal environmental laws and regulations for highway projects in Utah, pursuant to 23 U.S.C. 327. Actions taken by UDOT on FHWA's behalf pursuant to 23 U.S.C. 327 constitute Federal agency actions for purposes of Federal law. Notice is hereby given that UDOT has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the Purgatory Road; SR 9 to Southern Parkway project in the State of Utah. The Purgatory Road project proposes to improve regional system linkage and mobility between SR 9 and Southern Parkway. The project includes constructing a new three-lane roadway on new alignment between SR 9 and Southern Parkway. The proposed alignment would begin at SR 9 and follow the existing 5300 West alignment until the Quail Creek Industrial Park. The alignment would then run generally southward along the existing dirt road on the east side of the Purgatory Flat until approximately Landfill Road where it would swing to the west. The alignment would then cross the Virgin River via a new approximate 400-foot long, three-span structure to connect directly to Southern Parkway. These improvements were identified in the Environmental Assessment (EA) prepared for the project by UDOT as the

Purgatory Road Build Alternative, which combined Alternatives N2, M3, and R2. The actions by UDOT, and the laws under which such actions were taken, are described in the EA and UDOT Finding of No Significant Impact (FONSI) for the project (Finding of No Significant Impact for Purgatory Road; State Route 9 to Southern Parkway in Washington County, Utah, Project No. F–LC53(72)), issued on February 26, 2019, and in other documents in the UDOT project records. The EA and FONSI, and other project records are available by contacting UDOT at the address provided above. The EA and FONSI can also be viewed and downloaded from the project website at <https://www.purgatoryrd.com/>.

This notice applies to the EA, the FONSI, the Section 4(f) determination, the NHPA Section 106 review, the Endangered Species Act determination, and all other UDOT decisions and other actions with respect to the project as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to the following laws (including their implementing regulations):

1. *General:* National Environmental Policy Act, 42 U.S.C. 4321–4351; Federal-Aid Highway Act, 23 U.S.C. 109 and 23 U.S.C. 128.

2. *Air:* Clean Air Act, 42 U.S.C. 7401–7671q.

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966, 49 U.S.C. 303; 23 U.S.C. 138; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. *Wildlife:* Endangered Species Act, 16 U.S.C. 1531–1544 and Section 1536; Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d; Migratory Bird Treaty Act, 16 U.S.C. 703–712.

5. *Water:* Section 404 of the Clean Water Act, 33 U.S.C. 1344; E.O. 11990, Protection of Wetlands; Section 402 of the Clean Water Act, 33 U.S.C. 1342.

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, 16 U.S.C. 470f; Archeological Resources Protection Act of 1977, 16 U.S.C. 470aa–470mm; Archeological and Historic Preservation Act, 16 U.S.C. 469–469c.

7. *Noise:* Federal-Aid Highway Act of 1970, Public Law 91–605, 84 Stat. 1713.

8. *Executive Orders:* E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13287, Preserve America; E.O. 12898, Federal Actions to Address Environmental Justice and Low-Income Populations.

(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: March 26, 2019.

**Ivan Marrero,**

*Division Administrator, Federal Highway Administration, Salt Lake City, Utah.*

[FR Doc. 2019-06358 Filed 4-1-19; 8:45 am]

**BILLING CODE 4910-RY-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket No. FMCSA-1999-6156; FMCSA-2000-7006; FMCSA-2000-7363; FMCSA-2002-12294; FMCSA-2002-12844; FMCSA-2004-17195; FMCSA-2004-18885; FMCSA-2004-19477; FMCSA-2006-26066; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0292; FMCSA-2010-0187; FMCSA-2010-0287; FMCSA-2010-0327; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2011-0366; FMCSA-2011-0380; FMCSA-2013-0030; FMCSA-2014-0004; FMCSA-2014-0010; FMCSA-2014-0299; FMCSA-2015-0351; FMCSA-2016-0028; FMCSA-2016-0033; FMCSA-2016-0206]

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA announces its decision to renew exemptions for 71 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

**DATES:** Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, [fmcsamedical@dot.gov](mailto:fmcsamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

**SUPPLEMENTARY INFORMATION:**

## I. Public Participation

### A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-1999-6156; FMCSA-2000-7006; FMCSA-2000-7363; FMCSA-2002-12294; FMCSA-2002-12844; FMCSA-2004-17195; FMCSA-2004-18885; FMCSA-2004-19477; FMCSA-2006-26066; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0292; FMCSA-2010-0187; FMCSA-2010-0287; FMCSA-2010-0327; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2011-0366; FMCSA-2011-0380; FMCSA-2013-0030; FMCSA-2014-0004; FMCSA-2014-0010; FMCSA-2014-0299; FMCSA-2015-0351; FMCSA-2016-0028; FMCSA-2016-0033; FMCSA-2016-0206, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

### B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

## II. Background

On February 6, 2019, FMCSA published a notice announcing its decision to renew exemptions for 71 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (84 FR 2311). The public comment period ended on March 8, 2019, and no comments were received.

As stated in the previous notice, FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

## III. Discussion of Comments

FMCSA received no comments in this proceeding.

## IV. Conclusion

Based on its evaluation of the 71 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in 49 CFR 391.41(b)(10).

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of January and are discussed below. As of January 3, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 23 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (64 FR 54948; 65 FR 159; 65 FR 45817; 65 FR 77066; 66 FR 66969; 67 FR 71610; 69 FR 8260; 69 FR 17263; 69 FR 31447; 69 FR 53493; 69 FR 62742; 69 FR 64810; 71 FR 19604; 71 FR 27033; 71 FR 62147; 71 FR 62148; 72 FR 185; 73 FR 35194; 73 FR 35198; 73 FR 36954; 73 FR 36955; 73 FR 46973; 73 FR 48275; 73 FR 54889; 73 FR 61922; 73 FR 61925; 73 FR 63047; 73 FR 74563; 73 FR 74565; 73 FR 75806; 73 FR 75807; 75 FR 36779; 75 FR 44051; 75 FR 47883; 75 FR 50799; 75 FR 59327; 75 FR 63257; 75 FR 64396; 75 FR 65057; 75 FR 77590; 75 FR 77591; 75 FR 77949; 75 FR 77951; 75 FR 79081; 77 FR 5874; 77 FR 17109; 77 FR 17117; 77 FR 27845; 77 FR 38384; 77 FR 46153; 77 FR 60010; 77 FR 64582; 77 FR 64583; 77 FR 68202; 77 FR 70537; 77 FR 74730; 78 FR 41975; 78 FR 56986; 79 FR 18392; 79 FR 21996; 79 FR 29498; 79 FR 35220; 79 FR 38661; 79 FR 51643; 79 FR 56104; 79 FR 56117; 79 FR 59348; 79 FR 64001; 79 FR 65759; 79 FR 73689; 80 FR 48411; 81 FR 17237; 81 FR 28138; 81 FR 39320; 81 FR 59266; 81 FR 70253; 81 FR 71173; 81 FR 74494; 81 FR 80161; 81 FR 81230; 81 FR 96165; 81 FR 96191).

Robert J. Ambrose (MA)  
Nathan A. Buckles (IN)

David F. Cialdea (MA)  
 Robert J. Clarke (NY)  
 David R. Cox (OR)  
 Paul A. Gregerson (IA)  
 Victor B. Hawks (VA)  
 Jesse P. Jamison (TN)  
 Oscar Juarez (ID)  
 Mearl C. Kennedy (OH)  
 James W. Lappan (KS)  
 Joseph A. Leigh, Jr. (NC)  
 Bruce J. Lewis (RI)  
 John C. McLaughlin (SD)  
 Jack W. Murphy, Jr. (OH)  
 John C. Rodriguez (PA)  
 Jeffrey Sanders (NC)  
 Edward P. Schrader II (WA)  
 Randal J. Shabloski (PA)  
 Curtis L. Shannon (MN)  
 Julius Simmons, Jr. (SC)  
 Allen J. Stolz (WI)  
 Danny A. Wright (IN)

The drivers were included in docket numbers FMCSA-1999-6156; FMCSA-2000-7363; FMCSA-2004-17195; FMCSA-2004-18885; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0292; FMCSA-2010-0187; FMCSA-2010-0327; FMCSA-2011-0366; FMCSA-2011-0380; FMCSA-2013-0030; FMCSA-2014-0004; FMCSA-2014-0010; FMCSA-2015-0351; FMCSA-2016-0028; FMCSA-2016-0033; FMCSA-2016-0206. Their exemptions are applicable as of January 3, 2019, and will expire on January 3, 2021.

As of January 9, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (71 FR 63379; 72 FR 1051; 73 FR 78423; 75 FR 79083; 77 FR 74734; 79 FR 73686; 81 FR 96165):

David L. Cattoor (NV)  
 Arthur Dolengewicz (NY)  
 Terrence L. McKinney (TX)  
 Ellis T. McKneely (LA)  
 Ronald C. Morris (NV)  
 Steven M. Scholfield (KY)  
 David C. Stitt (KS)  
 Kevin L. Truxell (FL)  
 Bruce A. Walker (WI)  
 Lee A. Wiltjer (IL)

The drivers were included in docket number FMCSA-2006-26066. Their exemptions are applicable as of January 9, 2019, and will expire on January 9, 2021.

As of January 10, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (75 FR 69737; 76 FR 1499; 77 FR 74733; 79 FR 72756; 79 FR 73397; 80 FR 9304; 81 FR 96165):

Eric C. Hammer (MO)  
 Robert K. Ipock (NC)  
 Perry D. Jensen (WI)  
 Jesse L. Lichtenberger (PA)  
 James G. Pitchford (OH)  
 Frederick E. Schaub (IA)  
 Michael G. Somma (NY)  
 Jason E. Thomas (ND)  
 Richard L. Totels (TX)  
 Diane L. Wedebrand (IA)

The drivers were included in docket numbers FMCSA-2010-0287; FMCSA-2014-0299. Their exemptions are applicable as of January 10, 2019, and will expire on January 10, 2021.

As of January 12, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 20245; 65 FR 57230; 67 FR 67234; 69 FR 53493; 69 FR 62741; 69 FR 64742; 71 FR 62147; 71 FR 62148; 73 FR 61925; 73 FR 74565; 75 FR 59327; 75 FR 66423; 75 FR 72863; 76 FR 2190; 77 FR 68199; 77 FR 74273; 79 FR 73687; 81 FR 96165):

Timothy Bradford (TN)  
 Douglas K. Esp (MT)  
 Donald L. Hamrick (KS)  
 Gary L. Killian (NC)  
 Thomas L. Oglesby (GA)  
 Preston S. Salisbury (MT)  
 Kevin W. Schaffer (IL)  
 George A. Teti (FL)  
 David W. Ward (NC)  
 Ralph W. York (NM)

The drivers were included in docket numbers FMCSA-2000-7006; FMCSA-2004-18885; FMCSA-2010-0354. Their exemptions are applicable as of January 12, 2019, and will expire on January 12, 2021.

As of January 13, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 45817; 65 FR 77066; 67 FR 46016; 67 FR 57267; 67 FR 71610; 69 FR 71098; 71 FR 63379; 72 FR 1050; 72 FR 1054; 73 FR 78421; 75 FR 79079; 77 FR 76166; 79 FR 73687; 81 FR 96165):

David S. Brumfield (KY)  
 Arthur A. Sappington (IN)  
 William H. Smith (AL)  
 Edward C. Williams (AL)

The drivers were included in docket numbers FMCSA-2000-7363; FMCSA-2002-12294; FMCSA-2006-26066. Their exemptions are applicable as of January 13, 2019, and will expire on January 13, 2021.

As of January 14, 2019, and in accordance with 49 U.S.C. 31136(e) and

31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (69 FR 64806; 70 FR 2705; 72 FR 1056; 73 FR 76439; 75 FR 79084; 77 FR 75496; 79 FR 74169; 81 FR 96165); Christopher L. Depuy (OH); Larry J. Folkerts (IA); and Francis M. McMullin (PA).

The drivers were included in docket number FMCSA-2004-19477. Their exemptions are applicable as of January 14, 2019, and will expire on January 14, 2021.

As of January 17, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (67 FR 68719; 68 FR 2629; 69 FR 71100; 72 FR 1053; 73 FR 76440; 75 FR 80887; 77 FR 76167; 79 FR 74168; 81 FR 96165):

Howard F. Breitreutz (MN)  
 John E. Evenson (WI)  
 Craig M. Landry (LA)  
 Kenneth E. Vigue, Jr. (WA)

The drivers were included in docket number FMCSA-2002-12844. Their exemptions are applicable as of January 17, 2019, and will expire on January 17, 2021.

As of January 31, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (69 FR 17263; 69 FR 31447; 70 FR 44946; 71 FR 43557; 73 FR 42403; 75 FR 38602; 75 FR 72863; 75 FR 77492; 76 FR 2190; 76 FR 5425; 78 FR 800; 80 FR 603; 81 FR 96165):

Gary S. Alvarez (MA)  
 Brett K. Hasty (GA)  
 Gary D. Layton (TX)  
 Rocky D. Moorhead (NM)  
 Myron A. Smith (MN)  
 Jose M. Suarez (TX)  
 Richard L. Zacher (OR)

The drivers were included in docket numbers FMCSA-2004-17195; FMCSA-2010-0354; FMCSA-2010-0385. Their exemptions are applicable as of January 31, 2019, and will expire on January 31, 2021.

In accordance with 49 U.S.C. 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted;

or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: March 22, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019-06345 Filed 4-1-19; 8:45 am]

BILLING CODE 4910-EX-P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-12294; FMCSA-2004-19477; FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2007-27333; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0398; FMCSA-2009-0054; FMCSA-2010-0201; FMCSA-2010-0387; FMCSA-2010-0354; FMCSA-2010-0372; FMCSA-2011-0010; FMCSA-2011-0024; FMCSA-2011-0057; FMCSA-2012-0279; FMCSA-2012-0337; FMCSA-2012-0338; FMCSA-2013-0021; FMCSA-2013-0022; FMCSA-2013-0023; FMCSA-2013-0024; FMCSA-2013-0169; FMCSA-2014-0299; FMCSA-2014-0300; FMCSA-2014-0301; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2014-0305; FMCSA-2016-0030; FMCSA-2016-0214; FMCSA-2017-0014; FMCSA-2017-0016]

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of renewal of exemptions; request for comments.

**SUMMARY:** FMCSA announces its decision to renew exemptions for 74 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirements in one eye.

**DATES:** Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before May 2, 2019.

**ADDRESSES:** You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-12294; FMCSA-2004-19477; FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2007-27333; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0398; FMCSA-2009-0054; FMCSA-2010-0201; FMCSA-2010-0287; FMCSA-

2010-0354; FMCSA-2010-0372; FMCSA-2011-0010; FMCSA-2011-0024; FMCSA-2011-0057; FMCSA-2012-0279; FMCSA-2012-0337; FMCSA-2012-0338; FMCSA-2013-0021; FMCSA-2013-0022; FMCSA-2013-0023; FMCSA-2013-0024; FMCSA-2013-0169; FMCSA-2014-0299; FMCSA-2014-0300; FMCSA-2014-0301; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2014-0305; FMCSA-2016-0030; FMCSA-2016-0214; FMCSA-2017-0014; FMCSA-2017-0016 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, [fmcamedical@dot.gov](mailto:fmcamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

### **SUPPLEMENTARY INFORMATION:**

#### **I. Public Participation**

##### *A. Submitting Comments*

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-12294; FMCSA-2004-19477; FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2007-27333; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0398; FMCSA-2009-0054; FMCSA-2010-0201; FMCSA-2010-0287; FMCSA-2010-0354; FMCSA-2010-0372; FMCSA-2011-0010; FMCSA-2011-0024; FMCSA-2011-0057; FMCSA-2012-0279; FMCSA-2012-0337; FMCSA-2012-0338;

FMCSA-2013-0021; FMCSA-2013-0022; FMCSA-2013-0023; FMCSA-2013-0024; FMCSA-2013-0169; FMCSA-2014-0299; FMCSA-2014-0300; FMCSA-2014-0301; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2014-0305; FMCSA-2016-0030; FMCSA-2016-0214; FMCSA-2017-0014; FMCSA-2017-0016), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, put the docket number, FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-12294; FMCSA-2004-19477; FMCSA-2005-20027; FMCSA-2005-20560; FMCSA-2007-27333; FMCSA-2008-0106; FMCSA-2008-0231; FMCSA-2008-0398; FMCSA-2009-0054; FMCSA-2010-0201; FMCSA-2010-0287; FMCSA-2010-0354; FMCSA-2010-0372; FMCSA-2011-0010; FMCSA-2011-0024; FMCSA-2011-0057; FMCSA-2012-0279; FMCSA-2012-0337; FMCSA-2012-0338; FMCSA-2013-0021; FMCSA-2013-0022; FMCSA-2013-0023; FMCSA-2013-0024; FMCSA-2013-0169; FMCSA-2014-0299; FMCSA-2014-0300; FMCSA-2014-0301; FMCSA-2014-0302; FMCSA-2014-0304; FMCSA-2014-0305; FMCSA-2016-0030; FMCSA-2016-0214; FMCSA-2017-0014; FMCSA-2017-0016, in the keyword box, and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

### B. Viewing Documents and Comments

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### C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

## II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for five years if it finds that such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding vision found in 49

CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

The 74 individuals listed in this notice have requested renewal of their exemptions from the vision standard in 49 CFR 391.41(b)(10), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

### III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

### IV. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than five years from its approval date and may be renewed upon application. FMCSA grants exemptions from the vision standard for a two-year period to align with the maximum duration of a driver's medical certification. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 74 applicants has satisfied the renewal conditions for obtaining an exemption from the vision standard (see 65 FR 66286; 65 FR 78256; 66 FR 13825; 66 FR 16311; 67 FR 46016; 67 FR 57267; 68 FR 13360; 69 FR 62741; 69 FR 64806; 70 FR 2701; 70 FR 2705; 70 FR 12265; 70 FR 16887; 70 FR 17504; 70 FR 30997; 71 FR 62147; 72 FR 1056; 72 FR 11425; 72 FR 11426; 72 FR 12666; 72 FR 25831; 72 FR 27624; 73 FR 35194; 73 FR 46973; 73 FR 48273; 73 FR 54888; 73 FR 76440; 74 FR 7097; 74 FR 8302; 74 FR 8842; 74 FR 11988; 74 FR 15584; 74 FR 15586; 74 FR 19270; 74 FR 21427; 75 FR 44050; 75 FR 54958; 75 FR 64396; 75 FR 69737; 75 FR 70078; 75 FR 72863; 75 FR 80887; 76 FR 1499; 76 FR 2190; 76 FR 7894; 76 FR 9856; 76 FR 11215;

76 FR 12215; 76 FR 15361; 76 FR 17481; 76 FR 18824; 76 FR 20076; 76 FR 20078; 76 FR 21796; 76 FR 25762; 76 FR 28125; 76 FR 29024; 77 FR 60008; 77 FR 64582; 77 FR 68200; 77 FR 68202; 77 FR 70534; 77 FR 71671; 77 FR 74273; 77 FR 74731; 77 FR 74733; 78 FR 9772; 78 FR 10251; 78 FR 12811; 78 FR 12815; 78 FR 12822; 78 FR 14405; 78 FR 14410; 78 FR 16761; 78 FR 16762; 78 FR 16912; 78 FR 18667; 78 FR 20379; 78 FR 22596; 78 FR 22602; 78 FR 24296; 78 FR 24300; 78 FR 26106; 78 FR 29431; 78 FR 64274; 78 FR 77778; 79 FR 24298; 79 FR 56104; 79 FR 65759; 79 FR 65760; 79 FR 73397; 79 FR 73687; 80 FR 603; 80 FR 2473; 80 FR 3308; 80 FR 3723; 80 FR 6162; 80 FR 9304; 80 FR 12248; 80 FR 12251; 80 FR 12254; 80 FR 14220; 80 FR 14223; 80 FR 15859; 80 FR 15863; 80 FR 16500; 80 FR 16502; 80 FR 16509; 80 FR 18696; 80 FR 20558; 80 FR 20559; 80 FR 20562; 80 FR 22773; 80 FR 26320; 80 FR 29152; 80 FR 33011; 80 FR 45573; 81 FR 15401; 81 FR 45214; 81 FR 66726; 81 FR 96165; 82 FR 12678; 82 FR 13043; 82 FR 13048; 82 FR 17736; 82 FR 18818; 82 FR 18949; 82 FR 18954; 82 FR 23712; 82 FR 26224; 82 FR 28734). They have submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of May and are discussed below. As of May 7, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 47 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 66286; 65 FR 78256; 66 FR 13825; 66 FR 16311; 68 FR 13360; 69 FR 64806; 70 FR 2701; 70 FR 2705; 70 FR 12265; 70 FR 16887; 72 FR 1056; 72 FR 11425; 72 FR 11426; 72 FR 12666; 72 FR 25831; 73 FR 35194; 73 FR 46973; 73 FR 48273; 73 FR 54888; 73 FR 76440; 74 FR 7097; 74 FR 8302; 74 FR 8842; 74 FR 11988; 74 FR 15584; 74 FR 15586; 74 FR 21427; 75 FR 44050;

75 FR 54958; 75 FR 64396; 75 FR 69737; 75 FR 70078; 75 FR 72863; 75 FR 80887; 76 FR 1499; 76 FR 2190; 76 FR 7894; 76 FR 9856; 76 FR 11215; 76 FR 12215; 76 FR 15361; 76 FR 20076; 76 FR 20078; 76 FR 21796; 77 FR 60008; 77 FR 64582; 77 FR 68200; 77 FR 68202; 77 FR 70534; 77 FR 71671; 77 FR 74273; 77 FR 74731; 77 FR 74733; 78 FR 9772; 78 FR 10251; 78 FR 12811; 78 FR 12815; 78 FR 12822; 78 FR 14405; 78 FR 14410; 78 FR 16761; 78 FR 16762; 78 FR 18667; 78 FR 20379; 78 FR 22596; 78 FR 22602; 78 FR 24296; 78 FR 64274; 78 FR 77778; 79 FR 56104; 79 FR 65759; 79 FR 65760; 79 FR 73397; 79 FR 73687; 80 FR 603; 80 FR 2473; 80 FR 3308; 80 FR 3723; 80 FR 6162; 80 FR 9304; 80 FR 12248; 80 FR 12251; 80 FR 12254; 80 FR 14220; 80 FR 14223; 80 FR 15859; 80 FR 15863; 80 FR 16500; 80 FR 16502; 80 FR 16509; 80 FR 20562; 80 FR 29152; 80 FR 33011; 81 FR 15401; 81 FR 45214; 81 FR 66726; 81 FR 96165; 82 FR 12678; 82 FR 13043; 82 FR 13048; 82 FR 18818; 82 FR 18949; 82 FR 23712):

Neal S. Anderson (MN)  
 Michael L. Bergman (KS)  
 Joseph L. Beverly (FL)  
 Barry W. Borger (PA)  
 Gregory L. Cooper (PA)  
 Kenneth D. Craig (VA)  
 Marvin R. Daly (SC)  
 Deurice K. Dean (MD)  
 William A. Donovan (WA)  
 David M. Doub (IN)  
 Efrain Gonzalez (UT)  
 Ralph V. Graven (OR)  
 Michael D. Greene (VT)  
 Robert J. Hansen (MN)  
 Carl E. Hess (PA)  
 Michael R. Holmes (SD)  
 Shane M. Holm (WA)  
 Terry R. Hunt (FL)  
 Mark C. Jeffrey (MT)  
 James A. Jones (MD)  
 Joseph E. Jones (GA)  
 William D. Koiner (TX)  
 Roosevelt Lawson (AL)  
 Eugene R. Lydick (VA)  
 Roberto E. Martinez (WA)  
 Roy E. Mathews (FL)  
 David S. Mayo (VA)  
 Joe L. Meredith, Jr. (VA)  
 Gerald D. Milner (IL)  
 James G. Mitchell (AL)  
 Robert A. Moss (MO)  
 Gary L. Nicholas (MI)  
 Thomas G. Normington (WY)  
 Mark A. Omps (WV)  
 Johnny A. Peery (MD)  
 Bobby G. Pool, Sr. (TX)  
 Zeljko Popovac (VT)  
 Shannon L. Puckett (KY)  
 Franklin P. Reigle III (MD)  
 Bobby L. Rupe (TX)  
 George D. Ruth (PA)  
 James A. Smith (WA)  
 Benjamin Stone (VA)

Donald A. Uplinger II (OH)  
 Steven M. Veloz (CA)  
 Steven M. Vujicic (IL)  
 Charles F. Wotring (OH)

The drivers were included in docket numbers FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2004–19477; FMCSA–2005–20027; FMCSA–2007–27333; FMCSA–2008–0106; FMCSA–2008–0231; FMCSA–2008–0398; FMCSA–2009–0054; FMCSA–2010–0201; FMCSA–2010–0287; FMCSA–2010–0354; FMCSA–2010–0372; FMCSA–2011–0010; FMCSA–2012–0279; FMCSA–2012–0337; FMCSA–2012–0338; FMCSA–2013–0021; FMCSA–2013–0022; FMCSA–2013–0023; FMCSA–2013–0169; FMCSA–2014–0299; FMCSA–2014–0300; FMCSA–2014–0301; FMCSA–2014–0302; FMCSA–2014–0304; FMCSA–2016–0030; FMCSA–2016–0214. Their exemptions are applicable as of May 7, 2019, and will expire on May 7, 2021.

As of May 13, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (72 FR 12666; 72 FR 25831; 74 FR 15586; 76 FR 17481; 76 FR 21796; 76 FR 28125; 78 FR 24300; 80 FR 18696; 82 FR 17736; 82 FR 18949; 82 FR 26224):

Andrew R. Cook (VT)  
 David R. Ford (OH)  
 Douglas P. Fossum (SD)  
 Curtis L. Lamb (KS)  
 Eric D. Pohlmann (MN)  
 Michael O. Regentik (MI)  
 Esequiel Rodriguez, Jr. (TX)  
 Steven D. Scharber (MN)  
 George K. Sizemore (NC)  
 Donald E. Stone (VA)

The drivers were included in docket numbers FMCSA–2007–27333; FMCSA–2011–0024; FMCSA–2017–0014. Their exemptions are applicable as of May 13, 2019, and will expire on May 13, 2021.

As of May 19, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following five individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (76 FR 18824; 76 FR 29024; 78 FR 12815; 78 FR 22602; 79 FR 24298; 80 FR 20558; 82 FR 18949):

James O. Cook (GA)  
 Kevin R. Lambert (NC)  
 Scott W. Schilling (ND)  
 Randy E. Sims (WA)  
 Mark E. Studer (KS)

The drivers were included in docket numbers FMCSA–2011–0057; FMCSA–

2013–0022. Their exemptions are applicable as of May 19, 2019, and will expire on May 19, 2021.

As of May 20, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (78 FR 16912; 78 FR 29431; 80 FR 20559; 82 FR 18949): Dolan A. Gonzalez, Jr. (FL); and Paul Harpin (AZ)

The drivers were included in docket number FMCSA–2013–0024. Their exemptions are applicable as of May 20, 2019, and will expire on May 20, 2021.

As of May 25, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (82 FR 18954; 82 FR 28734):

Russell R. Dixon (VA); William M. Hanes (OH); and Dennis L. Spence (WA)

The drivers were included in docket number FMCSA–2017–0016. Their exemptions are applicable as of May 25, 2019, and will expire on May 25, 2021.

As of May 27, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (80 FR 22773; 80 FR 45573; 82 FR 18949):

Donald W. Donaldson (GA); Glen E. Robbins (WY); and Steven M. Tewhill (AR)

The drivers were included in docket number FMCSA–2014–0305. Their exemptions are applicable as of May 27, 2019, and will expire on May 27, 2021.

As of May 30, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (67 FR 46016; 67 FR 57267; 69 FR 62741; 70 FR 17504; 70 FR 30997; 71 FR 62147; 72 FR 27624; 74 FR 19270; 76 FR 9856; 76 FR 20076; 76 FR 25762; 78 FR 16762; 78 FR 26106; 80 FR 26320; 82 FR 18949):

Gerald S. Dennis (IA)  
 John K. Fank (IL)  
 Kenneth L. Nau (MD)  
 Kenneth E. Suter, Jr. (OH)

The drivers were included in docket numbers FMCSA–2002–12294; FMCSA–2005–20560; FMCSA–2011–0010. Their exemptions are applicable as of May 30, 2019, and will expire on May 30, 2021.

## V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must undergo an annual physical examination (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a certified Medical Examiner, as defined by 49 CFR 390.5, who attests that the driver is otherwise physically qualified under 49 CFR 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file or keep a copy of his/her driver's qualification if he/her is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

## VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

## VI. Conclusion

Based upon its evaluation of the 74 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above. In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: March 22, 2019.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2019-06346 Filed 4-1-19; 8:45 am]

**BILLING CODE 4910-EX-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket No. FMCSA-1998-3637; FMCSA-2000-7006; FMCSA-2001-10578; FMCSA-2002-12432; FMCSA-2002-12844; FMCSA-2004-19477; FMCSA-2005-23238; FMCSA-2006-26066; FMCSA-2008-0266; FMCSA-2008-0340; FMCSA-2010-0082; FMCSA-2010-0201; FMCSA-2010-0287; FMCSA-2010-0327; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2012-0040; FMCSA-2012-0337; FMCSA-2012-0339; FMCSA-2014-0007; FMCSA-2014-0010; FMCSA-2014-0298; FMCSA-2014-0299; FMCSA-2014-0300; FMCSA-2016-0207; FMCSA-2016-0210; FMCSA-2016-0212, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of final disposition.

**SUMMARY:** FMCSA announces its decision to renew exemptions for 52 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

**DATES:** Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, [fmcamedical@dot.gov](mailto:fmcamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

### SUPPLEMENTARY INFORMATION:

#### I. Public Participation

##### A. Viewing Documents and Comments

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FMCSA-2010-0201; FMCSA-2010-0287; FMCSA-2010-0327; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2012-0040; FMCSA-2012-0337; FMCSA-2012-0339; FMCSA-2014-0007; FMCSA-2014-0010; FMCSA-2014-0298; FMCSA-2014-0299; FMCSA-2014-0300; FMCSA-2016-0207; FMCSA-2016-0210; FMCSA-2016-0212, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

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## II. Background

On February 6, 2019, FMCSA published a notice announcing its decision to renew exemptions for 52 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (84 FR 2314). The public comment period ended on March 8, 2019, and no comments were received.

As stated in the previous notice, FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize

the colors of traffic signals and devices showing red, green, and amber.

### III. Discussion of Comments

FMCSA received no comments in this preceding.

### IV. Conclusion

Based on its evaluation of the 52 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in 49 CFR 391.41(b)(10).

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of February and are discussed below. As of February 5, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 32 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (63 FR 30285; 63 FR 54519; 65 FR 20245; 65 FR 57230; 65 FR 77069; 66 FR 53826; 66 FR 66966; 67 FR 57266; 67 FR 71610; 68 FR 69434; 69 FR 52741; 69 FR 64806; 69 FR 64810; 70 FR 2705; 70 FR 74102; 71 FR 5105; 71 FR 19600; 71 FR 53489; 71 FR 63379; 71 FR 66217; 72 FR 1051; 72 FR 1056; 73 FR 11989; 73 FR 36955; 73 FR 51336; 73 FR 51689; 73 FR 63047; 73 FR 74565; 73 FR 75803; 73 FR 76439; 73 FR 78423; 74 FR 6209; 75 FR 13653; 75 FR 25919; 75 FR 36779; 75 FR 39729; 75 FR 52062; 75 FR 54958; 75 FR 64396; 75 FR 65057; 75 FR 69737; 75 FR 70078; 75 FR 72863; 75 FR 77949; 75 FR 79081; 75 FR 79083; 75 FR 79084; 76 FR 1499; 76 FR 2190; 76 FR 4413; 77 FR 17107; 77 FR 38384; 77 FR 40946; 77 FR 52389; 77 FR 64582; 77 FR 68200; 77 FR 68202; 77 FR 70537; 77 FR 74273; 77 FR 74733; 77 FR 74734; 77 FR 75496; 78 FR 797; 79 FR 18391; 79 FR 35218; 79 FR 38659; 79 FR 46300; 79 FR 51643; 79 FR 53514; 79 FR 56104; 79 FR 59357; 79 FR 64001; 79 FR 65759; 79 FR 65760; 79 FR 69985; 79 FR 72756; 79 FR 73397; 79 FR 73686; 79 FR 73687; 79 FR 74169; 80 FR 603; 80 FR 3305; 80 FR 8927; 80 FR 9304; 81 FR 70248; 81 FR 72664; 81 FR 80161; 81 FR 81230; 81 FR 86063; 81 FR 90046; 81 FR 94013; 81 FR 96165; 81 FR 96180; 82 FR 12683; 82 FR 13048):

Kurtis A. Anderson (SD)  
Terry L. Anderson (PA)  
Ricky J. Childress (AL)  
Bryan K. DeBorde (WA)  
Roger P. Dittrich (IL)  
Craig E. Dorrance (MT)  
David L. Dykman (ID)  
Ricky L. Gillum (KY)  
Johnny J. Gowdy (MS)  
Harold J. Haier (NY)  
Ronald Holshouser (MO)  
Timothy L. Kelly (TX)

Lewis A. Kielhack (IL)  
John N. Lanning (CA)  
Bruce T. Loughary (AR)  
Samson B. Margison (OH)  
Joe A. McIlroy (NY)  
Charles J. Morman (FL)  
Timothy W. Nappier (MI)  
David J. Nocton (MN)  
Edward P. Paloskey (PA)  
Monte L. Purciful (IN)  
Kevin L. Quastad (IA)  
Antonio Rivera (PA)  
Carl W. Russell (OK)  
Randal C. Schmude (WI)  
Ronald B. Shafer (MI)  
Ranjodh Singh (CA)  
James D. St. Peter (NC)  
Lee F. Taylor (NJ)  
David J. Triplett (KY)  
David L. Von Hagen (IA)

The drivers were included in docket numbers FMCSA-1998-3637; FMCSA-2000-7006; FMCSA-2001-10578; FMCSA-2004-19477; FMCSA-2005-23238; FMCSA-2006-26066; FMCSA-2008-0266; FMCSA-2008-0340; FMCSA-2010-0082; FMCSA-2010-0201; FMCSA-2010-0287; FMCSA-2010-0327; FMCSA-2010-0354; FMCSA-2014-0007; FMCSA-2014-0010; FMCSA-2014-0298; FMCSA-2014-0299; FMCSA-2016-0207; FMCSA-2016-0210; FMCSA-2016-0212. Their exemptions are applicable as of February 5, 2019, and will expire on February 5, 2021.

As of February 7, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, Thomas J. Boss (IL) has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (67 FR 68719; 68 FR 2629; 69 FR 71100; 72 FR 1054; 74 FR 980; 76 FR 4414; 78 FR 798; 80 FR 5615; 82 FR 13048).

The driver was included in docket number FMCSA-2002-12844. The exemption is applicable as of February 7, 2019, and will expire on February 7, 2021.

As of February 11, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (77 FR 70534; 78 FR 9772; 80 FR 3308; 82 FR 13048): Douglas Eamens (NY); and Johnie Reed (VA)

The drivers were included in docket number FMCSA-2012-0337. Their exemptions are applicable as of February 11, 2019, and will expire on February 11, 2021.

As of February 18, 2019, and in accordance with 49 U.S.C. 31136(e) and

31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (80 FR 2473; 80 FR 18693; 82 FR 13048):

David C. Berger (PA)  
Raymond L. Bradshaw (TX)  
Jeffrey L. Coachman (NY)  
Kenneth Dionisi (MI)  
Wolfgang K. Faulkingham (ME)  
Jackie Lee (FL)  
Keith A. Looney (AR)  
Van C. Mac (IL)  
Luis Ramos (FL)  
Vantha Yeam (PA)

The drivers were included in docket number FMCSA-2014-0300. Their exemptions are applicable as of February 18, 2019, and will expire on February 18, 2021.

As of February 25, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (67 FR 54525; 68 FR 8794; 69 FR 64806; 70 FR 2705; 70 FR 8659; 72 FR 1056; 72 FR 5489; 73 FR 51689; 73 FR 63047; 73 FR 76439; 74 FR 6207; 75 FR 77942; 75 FR 79083; 75 FR 79084; 76 FR 5425; 76 FR 8809; 77 FR 23799; 77 FR 33558; 77 FR 75496; 78 FR 1919; 78 FR 12813; 78 FR 12817; 80 FR 3723; 82 FR 13048):

Lester W. Carter (CA)  
Dennis E. Fisher (NY)  
Dennis R. O'Dell, Jr. (OK)  
Jerry W. Parker (OH)  
Gary W. Phelps (PA)  
Charles D. Reddick (GA)  
Cameron R. Whitford (NY)

The drivers were included in docket number FMCSA-2002-12432; FMCSA-2004-19477; FMCSA-2008-0266; FMCSA-2010-0385; FMCSA-2012-0040; FMCSA-2012-0339. Their exemptions are applicable as of February 25, 2019, and will expire on February 25, 2021.

In accordance with 49 U.S.C. 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: March 22, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019-06356 Filed 4-1-19; 8:45 am]

BILLING CODE 4910-EX-P

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

[FTA Docket No. FTA 2019-0005]

#### Agency Information Collection Activity Under OMB Review

**AGENCY:** Federal Transit Administration, DOT.

**ACTION:** Notice of request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the extension of a currently approved information collection: Transit Research, Development, Demonstration and Training Projects.

**DATES:** Comments must be submitted before June 3, 2019.

**ADDRESSES:** To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Website:* [www.regulations.gov](http://www.regulations.gov).

Follow the instructions for submitting comments on the U.S. Government electronic docket site. (*Note:* The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at [www.regulations.gov](http://www.regulations.gov). Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202-366-7951.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

*Instructions:* You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received

your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to [www.regulations.gov](http://www.regulations.gov). You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit [www.regulations.gov](http://www.regulations.gov). Docket: For access to the docket to read background documents and comments received, go to [www.regulations.gov](http://www.regulations.gov) at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mary Leary (202) 366-2204 or email: [mary.leary@dot.gov](mailto:mary.leary@dot.gov).

**SUPPLEMENTARY INFORMATION:** Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

*Title:* Transit Research, Development, Demonstration and Training Projects (OMB Number: 2132-0546).

*Background:* 49 U.S.C. 5312(a) authorizes the Secretary of Transportation to make grants or contracts for research, development, demonstration and deployment projects, and for evaluation of technology of national significance to public transportation, that the Secretary determines will improve mass transportation service or help transportation service meet the total urban transportation needs at a minimum cost. In carrying out the provisions of this section, the Secretary is also authorized to request and receive appropriate information from any source. The information collected is submitted as part of the application for grants and cooperative agreements and is used to determine eligibility of applicants. Collection of this information also provides

documentation that the applicants and recipients are meeting program objectives and are complying with FTA Circular 6100.1D and other federal requirements.

*Respondents:* Federal Government Departments, agencies, and instrumentalities of the Government, including Federal laboratories; State and local governmental entities; providers of public transportation; private or non-profit organizations; institutions of higher education; and technical and community colleges.

*Estimated Annual Number of Respondents:* 175 respondents.

*Estimated Total Annual Burden:* 20,550 hours.

*Frequency:* Every Two Years.

Nadine Pembleton,

Director Office of Management Planning.

[FR Doc. 2019-06386 Filed 4-1-19; 8:45 am]

BILLING CODE P

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0000]

#### Agency Information Collection Activity: Veteran Employment Through Technology Education Courses (VET TEC) Employment Verification Form

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs

**ACTION:** Notice.

**SUMMARY:** Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before June 3, 2019.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). Please refer to "OMB Control No. 2900-XXXX" in any correspondence.

**FOR FURTHER INFORMATION CONTACT:**

Danny S. Green at (202) 421-1354.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

*Authority:* P.L. 115-48, section 116; 44 U.S.C. 3501-21.

*Title:* Veteran Employment Through Technology Education Courses (VET TEC) *Employment Verification Form:* (VA Form 22-10201).

*OMB Control Number:* 2900-0000.

*Type of Review:* New collection.

*Abstract:* VA Form 22-10201 will allow student veterans and SCOs to certify that a student veteran has obtained meaningful employment with the skills acquired during their training

program funded by the VET TEC program. The form will exist solely online and will be accessible via the *Vets.gov* website.

*Affected Public:* Individuals and households.

*Estimated Annual Burden:* 46,875 hours.

*Estimated Average Burden per Respondent:* 5 minutes.

*Frequency of Response:* One time.

*Estimated Number of Respondents:* 562,000.

By direction of the Secretary.

**Danny S. Green,**

*VA Interim Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.*

[FR Doc. 2019-06322 Filed 4-1-19; 8:45 am]

**BILLING CODE 8320-01-P**



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Part II

## Securities and Exchange Commission

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17 CFR Parts 229, 230, 232, et al.

FAST Act Modernization and Simplification of Regulation S-K; Final Rule

**SECURITIES AND EXCHANGE COMMISSION**

**17 CFR Parts 229, 230, 232, 239, 240, 249, 270, 274, and 275**

[Release No. 33-10618; 34-85381; IA-5206; IC-33426; File No. S7-08-17]

RIN 3235-AM00

**FAST Act Modernization and Simplification of Regulation S-K**

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rule.

**SUMMARY:** We are adopting amendments to modernize and simplify certain disclosure requirements in Regulation S-K, and related rules and forms, in a manner that reduces the costs and burdens on registrants while continuing to provide all material information to investors. The amendments are also intended to improve the readability and navigability of disclosure documents

and discourage repetition and disclosure of immaterial information. To provide for a consistent set of rules to govern incorporating information by reference and hyperlinking, we are also adopting parallel amendments to several rules and forms applicable to investment companies and investment advisers, including amendments that would require certain investment company filings to be submitted in HyperText Markup Language format.

**DATES:** The final rules are effective May 2, 2019, except for the amendments to 17 CFR 229.601(b)(2) and (b)(10)(iv); paragraph 4(a) of Instructions as to Exhibits of 17 CFR 249.220f; Instruction 6 to Item 1.01 of 17 CFR 249.308; Instruction 4 to Item 28 of 17 CFR 239.15A and 274.11A; Instruction 6 to Item 25.2 of 17 CFR 239.14 and 274.11a-1; Instruction 5 to Item 29(b) of 17 CFR 239.17a and 274.11b; Instruction 5 to Item 24(b) of 17 CFR 239.17b and 274.11c; Instruction 3 of Instructions as

to Exhibits of 17 CFR 239.24 and 274.5; new Instruction 3 to Item 26 of 17 CFR 239.17c and 274.11d; Instruction 3 to Item 16 of 17 CFR 239.23; Additional Instruction 3 to the Instructions as to Exhibits of 17 CFR 239.16; and Instruction 3 to IX. Exhibits of 17 CFR 274.12, which are effective April 2, 2019. For more information, see Section III (Other Matters).

*Compliance dates:* See Section IV (Transition Matters) and Section V (Compliance Dates).

**FOR FURTHER INFORMATION CONTACT:** Daniel Greenspan, Office of Rulemaking, Division of Corporation Finance, at (202) 551-3430; Michael C. Pawluk or Sean Harrison, Investment Company Rulemaking Office, Division of Investment Management, at (202) 551-6792; U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

**SUPPLEMENTARY INFORMATION:** We are adopting amendments to:

Commission reference	CFR citation (17 CFR)
Regulation S-K .....	§§ 229.10 through 229.1305.
Item 10 .....	§ 229.10.
Item 102 .....	§ 229.102.
Item 202 .....	§ 229.202.
Item 303 .....	§ 229.303.
Item 401 .....	§ 229.401.
Item 405 .....	§ 229.405.
Item 407 .....	§ 229.407.
Item 501 .....	§ 229.501.
Item 503 .....	§ 229.503.
Item 512 .....	§ 229.512.
Item 601 .....	§ 229.601.
Regulation M-A .....	§§ 229.1000 through 229.1016.
Item 1016 .....	§ 229.1016.
Regulation AB .....	§§ 229.1100 through 229.1125.
Item 1100 .....	§ 229.1100.
Regulation S-T .....	§§ 232.10 through 232.903.
Rule 11 .....	§ 232.11.
Rule 102 .....	§ 232.102.
Rule 105 .....	§ 232.105.
Rule 303 .....	§ 232.303.
Rule 312 .....	§ 232.312.
Rule 406 .....	§ 232.406.
Securities Act of 1933 <sup>1</sup> ("Securities Act"):	§ 230.405.
Rule 405 .....	
Rule 411 .....	§ 230.411.
Rule 491 .....	§ 230.491.
Form S-1 .....	§ 239.11.
Form S-3 .....	§ 239.13.
Form S-6 .....	§ 239.16.
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Form N-14 .....	§ 239.23.
Form S-4 .....	§ 239.25.
Form F-1 .....	§ 239.31.
Form F-3 .....	§ 239.33.
Form F-4 .....	§ 239.34.
Form F-7 .....	§ 239.37.
Form F-8 .....	§ 239.38.
Form F-10 .....	§ 239.40.
Form F-80 .....	§ 239.41.
Form SF-1 .....	§ 239.44.
Form SF-3 .....	§ 239.45.
Securities Exchange Act of 1934 <sup>2</sup> ("Exchange Act"):	§ 240.12b-23.
Rule 12b-23 .....	

Commission reference	CFR citation (17 CFR)
Schedule 14A .....	§ 240.14a–101.
Rule 16a–3 .....	§ 240.16a–3.
Form 3 .....	§ 249.103.
Form 4 .....	§ 249.104.
Form 5 .....	§ 249.105.
Form 8–A .....	§ 249.208a.
Form 10 .....	§ 249.210.
Form 20–F .....	§ 249.218.
Form 40–F .....	§ 249.240f.
Form 8–K .....	§ 249.308.
Form 10–Q .....	§ 249.308a.
Form 10–K .....	§ 249.310.
Form 10–D .....	§ 249.312.
Investment Company Act of 1940 <sup>3</sup> (“Investment Company Act”):	§ 270.0–4.
Rule 0–4.	
Form N–8B–2 .....	§ 274.12.
Securities Act and Investment Company Act:	§§ 239.15A and 274.11A.
Form N–1A.	
Form N–2 .....	§§ 239.14 and 274.11a–1.
Form N–3 .....	§§ 239.17a and 274.11b.
Form N–4 .....	§§ 239.17b and 274.11c.
Form N–5 .....	§§ 239.24 and 274.5.
Form N–6 .....	§§ 239.17c and 274.11d.
Exchange Act and Investment Company Act:	
Form N–CSR §§ 249.331 and 274.128.	
Investment Advisers Act of 1940 <sup>4</sup> (“Investment Advisers Act”):	§ 275.0–6.
Rule 0–6 § 275.0–6.	

We are also adopting 17 CFR 229.105 (new “Item 105”) to Regulation S–K) and rescinding the following:

Commission reference	CFR citation (17 CFR)
Exchange Act:	
Rule 12b–32 .....	§ 240.12b–32.
Investment Company Act:	
Rule 8b–23 .....	§ 270.8b–23.
Rule 8b–24 .....	§ 270.8b–24.
Rule 8b–32 .....	§ 270.8b–32.

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<sup>2</sup> 15 U.S.C. 78a *et seq.*

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<sup>4</sup> 15 U.S.C. 80b–1 *et seq.*

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**I. Introduction**

On October 11, 2017, the Commission proposed amendments to modernize and simplify certain disclosure requirements in Regulation S–K and related rules and forms,<sup>5</sup> as mandated by the 2015 Fixing America’s Surface Transportation Act (the “FAST Act”).<sup>6</sup> The proposals were based on the Commission’s report to Congress, published on November 23, 2016 (the

“FAST Act Report”),<sup>7</sup> which contained “specific and detailed recommendations on modernizing and simplifying the requirements in Regulation S–K in a manner that reduces the costs and burdens on companies while still providing all material information” and “[recommendations] on ways to improve the readability and navigability of disclosure and to discourage repetition and the disclosure of immaterial information.”<sup>8</sup> The proposals were also informed by the Commission’s experience with Regulation S–K arising from the Division of Corporation Finance’s disclosure review program and our staff’s broader review of the Commission’s disclosure regime.<sup>9</sup> In addition, the Commission proposed parallel amendments to several rules and forms applicable to investment companies and investment advisers to provide for a consistent set of rules governing incorporation by reference and hyperlinking, including proposed amendments that would require certain investment company filings to be submitted in HyperText Markup Language (“HTML”) format.<sup>10</sup>

Commenters on the Proposing Release generally supported the proposed amendments and the Commission’s efforts to improve and modernize the disclosure requirements of Regulation S–K.<sup>11</sup> While commenters were largely supportive of the proposals, we also received a number of suggestions for modifying the amendments in ways that commenters believed would clarify the revised disclosure requirements,

simplify compliance, or more consistently reflect the policy objectives cited in the Proposing Release.

After taking into consideration the public comments, we are adopting the majority of the amendments as proposed. As we discuss further below, in certain cases we are adopting amendments with modifications from those proposed and, in other cases, we have chosen not to adopt the proposed amendments. In the discussion that follows, we first address the proposals we are adopting with modifications from those proposed, then the amendments we are adopting as proposed, and, finally, the proposed amendments we have elected not to adopt.

The changes we are adopting, consistent with the Commission’s mandate under the FAST Act, are intended to improve the quality and accessibility of disclosure in filings by simplifying and modernizing our requirements. The amendments also clarify ambiguous disclosure requirements, remove redundancies, and further leverage the use of technology. Taken together, we believe these rule changes should result in significant savings of time and money for registrants. We also believe they will increase investor access to information without reducing the availability of material information.

The following table highlights some of the changes we are adopting, as described more fully in Section II (Final Amendments) and elsewhere in this release:

Rule	Summary description of amended rules <sup>12</sup>	Principal objective	Discussed below in section
Regulation S–K, Item 303 and Form 20–F	Registrants will generally be able to exclude discussion of the earliest of three years in MD&A if they have already included the discussion in a prior filing.	Simplify disclosure requirements to reduce repetition, reduce costs and burdens to registrants, focus disclosure on material information and improve readability.	II.A.1.

<sup>5</sup> See *Fast Act Modernization and Simplification of Regulation S–K*, Release No. 33–10425 (Oct. 11, 2017) [82 FR 50998 (Nov. 2, 2017)] (“Proposing Release”).

<sup>6</sup> Public Law 114–94, Sec. 72003, 129 Stat. 1312 (2015).

<sup>7</sup> See *Report on Modernization and Simplification of Regulation S–K* (Nov. 23, 2016), available at <https://www.sec.gov/reportspubs/sec-fast-act-report-2016.pdf> (the “FAST Act Report”).

<sup>8</sup> See FAST Act section 72003(c). Section 72003(c) required the Commission to issue the FAST Act Report and Section 72003(d) required the Commission to issue a proposed rule to implement the recommendations contained in the FAST Act Report.

<sup>9</sup> See the Proposing Release, *supra* note 5, at 50989. We are continuing to consider additional changes to our disclosure regime in connection with recent rule releases and requests for comment. See, e.g., *Request for Comment on Possible Changes to Industry Guide 3 (Statistical Disclosure by Bank Holding Companies)*, Release No. 33–10321 (Mar. 1, 2017) [82 FR 12757 (Mar. 7, 2017)]; *Business and Financial Disclosure Required by Regulation S–K*, Release No. 33–10064 (Apr. 13, 2016) [81 FR 23916 (Apr. 22, 2016)] (the “Concept Release”); and *Request for Comment on Subpart 400 of Regulation S–K Disclosure Requirements Relating to Management, Certain Security Holders and Corporate Governance Matters*, Release No. 33–10198 (Aug. 25, 2016) [81 FR 59927 (Aug. 31, 2016)] (the “Regulation S–K Subpart 400 Release”).

<sup>10</sup> The Commission has adopted requirements for exhibit hyperlinks and HTML format for operating companies. See *Exhibit Hyperlinks and HTML Format*, Release No. 33–10322 (Mar. 1, 2017) [82 FR 14130 (Mar. 17, 2017)] (the “Exhibit Hyperlinks Adopting Release”) (adopting amendments to require registrants to hyperlink to each exhibit listed in the exhibit index and, to enable the inclusion of hyperlinks, requiring registrants to submit all such filings in HTML format).

<sup>11</sup> Comment letters related to the Proposing Release are available at <https://www.sec.gov/comments/s7-08-17/s70817.htm>. Unless otherwise indicated, comment letters cited in this release are to the Proposing Release.

Rule	Summary description of amended rules <sup>12</sup>	Principal objective	Discussed below in section
Regulation S-K, Items 601(b)(10) and 601(b)(2) and investment company registration forms.	Registrants will be able to omit confidential information in material contracts and certain other exhibits without submitting a confidential treatment request to the Commission, so long as the information is (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.	Substantially reduce the burden borne by registrants in preparing and responding to confidential treatment requests while still providing all material information to investors.	II.A.2.
Regulation S-K, Item 601(b)(10) .....	Only newly reporting registrants will be required to file material contracts that were entered within two years of the applicable registration statement or report.	Eliminate duplicative and unnecessary disclosure and reduce costs and burdens to registrants while still providing all material information to investors.	II.B.5.c.
Regulation S-K, Item 601(a)(5) and investment company forms.	Registrants will not be required to file attachments to their material agreements if such attachments do not contain material information or were not otherwise disclosed.	Reduce costs and burdens to registrants while still providing all material information to investors.	II.B.5.b.i.
Regulation S-K, Item 102 .....	Registrants will need to provide disclosure about a physical property only to the extent that it is material to the registrant.	Clarify and simplify the disclosure requirement to reduce costs and burdens to registrants, while focusing on material information.	II.B.1.
Forms 8-K, 10-Q, 10-K, 20-F and 40-F.	Registrants will be required to disclose on the form cover page the national exchange or principal U.S. market for their securities, the trading symbol, and title of each class of securities.	Improve investors' efforts to search news websites and stock market databases for information about registrants and distinguish among similarly named companies.	II.B.4.a.iii. & II.B.7.a.
Securities Act Rule-411(b)(4); Exchange Act Rules 12b-23(a)(3), and 12b-32; Investment Company Act Rule 0-4; and Regulation S-T Rules 102 and 105.	Registrants will no longer be required to file as an exhibit any document or part thereof that is incorporated by reference in a filing, but instead will be required to provide hyperlinks to documents incorporated by reference.	Improve readability and navigability of disclosure documents and discourage repetition.	II.B.6.i, & II.B.6.b.ii.
Forms 10-K, 10-Q, 8-K, 20-F and 40-F.	Registrants will be required to tag all cover page data in Inline XBRL.	Further enhance investors' use of interactive data to identify, count, sort, compare, and analyze registrants and their disclosures.	II.B.7.a.
Regulation S-T Rules 102, 105, 201, 202 and 311; Form N-CSR; and investment company registration forms.	Investment companies will be required to file reports on Form N-CSR and registration statements and amendments thereto in HTML format and provide hyperlinks to exhibits and other information incorporated by reference.	Improve navigability of disclosure .....	II.B.7.b.

**II. Final Amendments**

*A. Adoption of Proposals With Modifications*

1. Management's Discussion and Analysis of Financial Condition and Results of Operations (Item 303)

a. Year-to-Year Comparisons (Instruction 1 to Item 303(a))

i. Proposed Amendments

Item 303(a) requires registrants to discuss their financial condition, changes in financial condition, and

results of operations.<sup>13</sup> Instruction 1 to Item 303(a) states that the discussion and analysis shall be of the financial statements and other statistical data that the registrant believes will enhance a reader's understanding of its financial condition, changes in financial condition, and results of operations. This instruction also provides that, generally, the discussion shall cover the three-year period covered by the financial statements and either use year-to-year comparisons or any other format that in the registrant's judgment would enhance a reader's understanding. The instruction states that reference to the five-year selected financial data may be necessary where trend information is relevant.

The Commission proposed to amend Item 303 to clarify that discussion of the earliest year would not be required in

certain situations.<sup>14</sup> Specifically, when financial statements included in a filing cover three years,<sup>15</sup> discussion about the earliest year would not have been required under the proposed amendments if (i) that discussion was

<sup>14</sup> See Proposing Release, *supra* note 5, Section II.B.1., n. 46 through 53. See also FAST Act Report, *supra* note 7, at Recommendation C.1.

<sup>15</sup> The proposed amendments to Item 303(a)(3) would not affect smaller reporting companies, as smaller reporting companies may limit their disclosure to the two-year period covered by their financial statements. See Instruction 1 to Item 303(a) of Regulation S-K. See also Rule 12b-2 under the Exchange Act and Rule 405 under the Securities Act. Similarly, the proposed amendments would not affect emerging growth companies that provide two years of audited financial statements. Emerging growth companies are only required to provide two years of audited financial statements in an initial public offering of common equity securities and may limit their MD&A to only those audited periods presented in the financial statements. Pub. L. 112-106, Sec. 102(b)-(c), 126 Stat. 306 (2012). See also Instruction 1 to Item 303(a) of Regulation S-K.

<sup>12</sup> The information in this chart is not comprehensive and is intended only to highlight some of the more significant aspects of the final amendments. It does not reflect all of the amendments or all of the rules and forms that are affected. All changes are discussed in their entirety below. As such, this table should be read together with the referenced sections and the complete text of this release.

<sup>13</sup> 17 CFR 229.303(a).

not material to an understanding of the registrant's financial condition, changes in financial condition, and results of operations, and (ii) the registrant had filed its prior year Form 10-K<sup>16</sup> on EDGAR and that Form 10-K included in its Management's Discussion and Analysis ("MD&A") a discussion of the earliest of the three years included in the financial statements of the current filing. By allowing registrants to eliminate MD&A disclosure about the earliest year in these situations, the proposal was intended to discourage repetition of disclosure that is no longer material, which we believe would further our mandate under the FAST Act to modernize and simplify Regulation S-K in a manner that reduces costs and burdens on companies while still providing all material information.

For the reasons discussed in the Proposing Release, the Commission also proposed to eliminate the reference to five-year selected financial data in Instruction 1 to Item 303(a).<sup>17</sup> In addition, the Commission proposed to simplify Instruction 1 to Item 303(a) to emphasize that registrants may use any presentation that, in the registrant's judgment, would enhance a reader's understanding.<sup>18</sup>

#### ii. Comments

The proposal generated a wide range of responses among commenters. While some commenters supported the amendments as proposed,<sup>19</sup> many commenters sought revisions or clarifications to the proposed rule. In particular, several commenters focused their remarks on the proposed conditions by which registrants could omit discussion of the earliest of the three years of financial statements covered by a filing. One commenter opposed the amendments to Item 303, asserting that retaining the discussion of the earliest year would help investors "understand the validity of analysis" in the MD&A where a company's circumstances have changed.<sup>20</sup>

A number of commenters found the first proposed condition to be problematic, largely due to uncertainty over the phrase "material to an

understanding."<sup>21</sup> While many of these commenters supported the concept underlying the proposal, they advocated that the Commission first refine or clarify the materiality condition to ensure that its implementation would have the effect the Commission intended.<sup>22</sup> These commenters questioned how the "material to an understanding" condition would be applied in practice and were uncertain how it differed, if at all, from the standard of materiality registrants already use to fulfill their disclosure obligations.<sup>23</sup> Several commenters advised that without further clarification registrants would be unlikely to omit the discussion of the earliest year for fear that their judgment would be challenged.<sup>24</sup> Along these lines, one commenter predicted that, because of litigation risk, registrants would find it much easier to simply repeat the disclosure made in the prior year rather than expose their assessment of materiality to second-guessing.<sup>25</sup>

To mitigate these concerns and add more certainty to the process, some commenters favored revising the proposal to make the condition less subjective,<sup>26</sup> while others suggested adding conditions that would preclude registrants from omitting disclosure of the earliest year in certain specified

situations.<sup>27</sup> Other commenters favored removing the materiality condition altogether because they believed it was unnecessary and would only create confusion.<sup>28</sup> These commenters stated that registrants should be permitted to omit the discussion of the earliest year covered by the financial statement in a filing based solely on the condition that the disclosure was already included in a previous filing. One such commenter noted that it is unnecessary to embed an explicit materiality reference within the proposed rule because materiality is already the overarching principle for a registrant's disclosure and has been well defined by federal securities law.<sup>29</sup> The commenter went on to state that, as such, materiality is always a factor in disclosure, whether or not the proposed revision makes explicit reference to it. In this context, another commenter asserted that adding an additional materiality assessment would only add ambiguity and complexity to the registrant's decision whether to include a discussion of the earliest period presented.<sup>30</sup>

Several commenters supported expanding the second of the two proposed conditions for omission of the earliest year's discussion to allow registrants to use filings other than the prior year's Form 10-K as the reference document.<sup>31</sup> These commenters recommended that any filing available on EDGAR (*e.g.*, Form S-1, Form S-4, Form 8-K, Form 10, etc.) that contains the relevant MD&A discussion should suffice.<sup>32</sup>

Finally, several commenters expressed support for the proposal to eliminate the reference to five-year selected financial data in Instruction 1 to Item 303(a), and no commenters opposed it.<sup>33</sup>

#### iii. Final Amendments

We are adopting amendments to Item 303 in substantially the form proposed, but with modifications in response to

<sup>21</sup> See, *e.g.*, letter from Ernst & Young LLP ("E&Y") (noting that the proposed standard "could be challenging to apply in practice . . . registrants could struggle to consistently evaluate whether discussion of the earliest of the three years is 'material to an understanding'. . .").

<sup>22</sup> See, *e.g.*, letters from E&Y (raising a series of interpretive questions about the proposal) and Deloitte & Touche LLP ("Deloitte") (questioning whether the phrase "material to an understanding" was intended to convey any special considerations beyond a registrant's customary assessment of materiality).

<sup>23</sup> See, *e.g.*, letter from E&Y (noting the abundance of instances in Regulation S-K where the disclosure requirements reference some variation of materiality, creating a lack of clarity in many cases about whether the Commission intended registrants to evaluate materiality in a different context than its general application under federal securities law).

<sup>24</sup> See, *e.g.*, letters from BDO USA, LLP ("BDO"), CNA Financial Corporation ("CNA"), Cravath, Swaine & Moore LLP ("Cravath"), Institute of Management Accountants ("IMA"), KPMG LLP ("KPMG"), Piercy Bowler Taylor and Kern, CPAs ("Piercy Bowler"), and Society for Corporate Governance ("Society for Corp. Gov.").

<sup>25</sup> See letter from IMA. See also letter from Society for Corp. Gov. (suggesting that modifying the default requirement of Item 303 from "disclosure of the earliest year's discussion, unless not material" to "omission of the earliest year's discussion, unless material" may more effectively accomplish the Commission's objective of reducing the amount of immaterial and repetitive disclosure).

<sup>26</sup> See, *e.g.*, letter from Financial Executive International ("Financial Executives") (requesting that the rule be revised to permit the omission of the discussion about the earliest year unless there has been a material change to the previous disclosures).

<sup>27</sup> See, *e.g.*, letter from Council of Institutional Investors ("CII") (suggesting that registrants not be allowed to exclude discussion of the earliest year if there has been a material change to either of the two earlier years due to a restatement or a retrospective adoption of a new accounting principle).

<sup>28</sup> See, *e.g.*, letters from BDO, Center for Audit Quality ("CAQ"), and Northrop Grumman Corporation ("Grumman").

<sup>29</sup> See letter from CAQ.

<sup>30</sup> See letter from BDO.

<sup>31</sup> See letters from BDO, Cravath, Deloitte, E&Y, KPMG, Piercy Bowler, and Sullivan & Cromwell LLP ("Sullivan").

<sup>32</sup> *Id.*

<sup>33</sup> See letters from CAQ, CCMC, CNA, Cravath, Davis Polk, Fenwick, Financial Executives, Securities Industry and Financial Markets Association ("SIFMA"), and Sullivan.

<sup>16</sup> 17 CFR 249.310.

<sup>17</sup> See Proposing Release, *supra* note 5, Section II.B.1., at 50993.

<sup>18</sup> *Id.*

<sup>19</sup> See letters from American Fuel and Petrochemical Manufacturers ("American Fuel"), Center for Capital Markets Competitiveness ("CCMC"), Davis Polk & Wardwell ("Davis Polk"), FedEx Corporation ("FedEx"), Fenwick & West LLP ("Fenwick"), Nasdaq, Inc. ("Nasdaq"), and UnitedHealth Group ("UnitedHealth").

<sup>20</sup> See letter from Public Citizen.

comments received. We are adopting as proposed the revision to Instruction 1 of Item 303 that eliminates the reference to year-to-year comparisons. Instruction 1 will now state that registrants may use any presentation that in the registrant's judgment enhances a reader's understanding of the registrant's financial condition, changes in financial condition, and results of operations, without suggesting that any one mode of presentation is preferable to another. We anticipate that many registrants will continue to provide year-to-year comparisons, as this is a familiar and, in many cases, appropriate method of presentation. However, we recognize that this presentation may not always be the most effective format, depending on the unique circumstances of a particular registrant. Also, as proposed, we are deleting the reference to five-year selected financial data in Instruction 1 to Item 303(a). Item 303(a)(3)(ii) already requires disclosure of known trends and uncertainties, so we do not anticipate that the removal of similar wording from Instruction 1 will discourage trend disclosure or otherwise reduce disclosure of material information.

We are revising Instruction 1 to Item 303(a) to allow registrants who are providing financial statements covering three years in a filing to omit discussion of the earliest of the three years if such discussion was already included in any other of the registrant's prior filings on EDGAR that required disclosure in compliance with Item 303 of Regulation S-K.<sup>34</sup> Registrants electing not to include a discussion of the earliest year in reliance on this instruction must, however, identify the location in the prior filing where the omitted discussion may be found. These amendments reflect two changes from the proposal.

First, we are expanding the condition regarding the earliest year discussion to allow registrants to rely on any prior EDGAR filings that include such discussion. We agree with commenters who recommended expanding this condition to encompass MD&A of the earliest year included in filings other than Form 10-K.<sup>35</sup> We do not believe it is necessary to designate the registrant's prior Form 10-K as the only filing that may serve as the location of the omitted disclosure, so long as the registrant clearly identifies the prior filing that includes the relevant discussion.

<sup>34</sup> Instruction 1 to Item 303(a), as revised. Amended Form 20-F will include analogous wording in new Instruction 6 to Item 5. See *infra* Section II.A.1.b. of this release.

<sup>35</sup> See *supra* note 31.

Second, we are not adopting, as an explicit condition, that the omitted discussion must not be "material to an understanding" of the registrant's financial condition, changes in financial condition, and results of operations. This is not to suggest, however, that materiality is not relevant to management's judgment about what disclosure is provided in MD&A. Materiality remains, as always, the primary consideration. Rather, this change recognizes that the language of the proposed condition was superfluous and never intended to modify, supplement, or alter the overarching materiality analysis that management must undertake with respect to the information it provides investors in MD&A. As several commenters pointed out, this superfluous language may serve to create confusion for registrants and discourage them from tailoring their disclosure in a manner that is most useful for investors.<sup>36</sup>

Although a discussion of the earliest year of the financials could in some circumstances be material, in many cases the entirety of the discussion of the earliest year that was presented in the MD&A of a prior filing would not need to be reiterated if, in management's view, that discussion is not necessary to understand the financial condition, changes in financial condition, and results of operations.<sup>37</sup> This is the standard that applies to all of MD&A,<sup>38</sup> and our amendments do not change that standard. A registrant's obligation is to provide investors with all material information, customized in light of the company's particular circumstances, and presented in a manner that best reflects the discussion and analysis of the business as seen through the eyes of those who manage that business.<sup>39</sup> We

<sup>36</sup> See *supra* note 21. For similar reasons, we are not adopting different or additional conditions on the omission of the earliest year discussion as suggested by several commenters. See *supra* notes 26 and 27.

<sup>37</sup> For investors who find the earliest year discussion useful in understanding the MD&A, this information will remain readily available from prior filings on EDGAR. See *supra* note 20.

<sup>38</sup> See Item 303(a): "The discussion . . . shall provide such other information that the registrant believes to be necessary to an understanding of its financial condition, changes in financial condition and results of operations."

<sup>39</sup> See *Commission Guidance Regarding Management's Discussion and Analysis of Financial Condition and Results of Operation*, Release No. 33-8350 (Dec. 19, 2003) [68 FR 75056 (Dec. 29, 2003)] ("2003 MD&A Interpretive Release"), Sections I.B and III.B.2. See also *Concept Release on Management's Discussion and Analysis of Financial Condition and Operations*, Release No. 6711 (Apr. 17, 1987) [52 FR 13715, 13717] (Apr. 23, 1987)] ("MD&A Concept Release") ("an opportunity to look at the company through the eyes of management by providing both a short and long-term analysis of the business of the company").

continue to encourage registrants to take the opportunity to reevaluate their disclosure in light of these amendments and determine whether a discussion of the earliest year's information remains material.<sup>40</sup> We believe these amendments underscore the continuing relevance of the Commission's guidance in the 2003 MD&A Release that "it is increasingly important for companies to focus their MD&A on material information. In preparing MD&A, companies should evaluate issues presented in previous periods and consider reducing or omitting discussion of those that may no longer be material or helpful, or revise discussions where a revision would make the continuing relevance of an issue more apparent."<sup>41</sup>

We believe the revisions to Item 303 that we are adopting give registrants the flexibility to tailor their presentation in MD&A in a manner that is most suitable for their varying circumstances, while at the same time continuing to require that they provide all of the information necessary to an understanding of their financial condition, changes in financial condition and results of operations. In that respect, we view the elimination of references to year-to-year comparisons and the new language in Instruction 1 of Item 303 allowing registrants to omit discussion of the earliest of the three years covered by the financial statements as complementary.

#### b. Application to Foreign Private Issuers

##### i. Proposed Amendments

The disclosure requirements for Item 5 of Form 20-F (Operating and Financial Review and Prospects) are substantively comparable to the MD&A requirements under Item 303 of Regulation S-K.<sup>42</sup> To maintain a consistent approach to MD&A for domestic registrants and foreign private issuers, the Commission proposed changes to Form 20-F to conform with the proposed amendments to Instruction 1 to Item 303(a).<sup>43</sup>

<sup>40</sup> See 2003 MD&A Interpretive Release, Sections I.B. and III.B.2.; and see *Proposing Release*, *supra* note 5, at 50993.

<sup>41</sup> See 2003 MD&A Release, Section III.B.2.

<sup>42</sup> When the Commission revised the wording of Item 5 of Form 20-F in 1999, the adopting release noted that the requirements correspond with Item 303 of Regulation S-K. See *International Disclosure Standards*, Release No. 33-7745 (Sept. 28, 1999) [64 FR 53900 (Oct. 5, 1999)], at 53904.

<sup>43</sup> The Commission did not propose similar changes to Form 40-F. Form 40-F generally permits Canadian issuers to use Canadian disclosure documents to satisfy the Commission's registration and disclosure requirements. As a result, the MD&A contained in Form 40-F is largely prepared in accordance with Canadian disclosure standards.

## ii. Comments

Several commenters supported the proposal to make conforming changes to Form 20-F, and no commenters opposed.<sup>44</sup>

## iii. Final Amendments

We are adopting the proposed revisions to Item 5 of Form 20-F, as modified to be consistent with the amendments to Item 303. In its amended form, Item 5 of Form 20-F will provide that, when a filing includes financial statements covering three years, discussion about the earliest year may be omitted if such discussion was already included in the registrant's prior year Form 20-F filed on EDGAR or in any other of the registrant's prior filings on EDGAR that required disclosure in compliance with Item 5 of Form 20-F or with Item 303 of Regulation S-K. Registrants electing not to include a discussion of the earliest year must, however, include a statement that identifies the location in the prior filing where the omitted discussion may be found. Similar to revised Item 303, we are revising the instructions to Item 5 to emphasize that registrants may use any presentation that, in the registrant's judgment, would enhance a reader's understanding.

## 2. Redaction of Confidential Information in Material Contract Exhibits

### a. Proposed Amendment

As a general matter, current Item 601(b)(10) requires registrants to file as an exhibit to their applicable disclosure document each of their material contracts entered into within the preceding two years or which is to be performed, at least in part, in the future. It is not unusual for some of the information contained in such exhibits to be highly sensitive, most often for competitive reasons. If such information is not material and is covered by an exemption from the Freedom of Information Act,<sup>45</sup> a registrant may request confidential treatment which, if granted by the Commission, would allow the registrant to redact specific information from the material contract exhibit that it files publicly on EDGAR.

Exchange Act Rule 24b-2 and Securities Act Rule 406 set forth the

exclusive procedures for obtaining confidential treatment in regard to exhibits filed under the Exchange Act and Securities Act. Registrants who wish to avail themselves of these rules must submit a detailed application to the Commission that identifies the particular text for which confidential treatment is sought, a statement of the legal grounds for the exemption,<sup>46</sup> and an explanation of why, based on the facts and circumstances of the particular case, disclosure of the information is unnecessary for the protection of investors.<sup>47</sup> Upon receipt of the application, known as a "confidential treatment request" or "CTR," Commission staff will evaluate whether the request appears appropriate and whether to issue comments on the application.

The Commission proposed revisions to Item 601(b)(10) that would permit registrants to omit confidential information from material contracts filed pursuant to that item without the need to submit a CTR, if the information (i) is not material and (ii) would be competitively harmful if publicly disclosed. Although registrants would not be required to file a confidential treatment request in accordance with Rule 406 or Rule 24b-2 in connection with the redacted exhibit, the responsibility of a registrant to determine whether all material information has been disclosed and whether it may redact the information under the proposed rules would remain unchanged.<sup>48</sup> Redactions made in accordance with revised Item 601(b)(10) should include no more information than necessary to prevent competitive harm to the registrant.

Under the proposal, the requirements for marking exhibits subject to confidential treatment would remain in place as well. Just as registrants must do under the current rules, the proposed amendments would require registrants to:

- Mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted;
- include a prominent statement on the first page of the redacted exhibit that

certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed; and

- indicate with brackets where the information has been omitted from the filed version of the exhibit.

Under the proposed revisions, the Commission staff would continue its selective review of registrant filings and would selectively assess whether redactions from exhibits appear to be limited to information that is not material and that would cause competitive harm if publicly disclosed. Upon request, registrants would be expected to promptly provide supplemental materials to the staff similar to those currently required in a CTR, including an unredacted copy of the exhibit and an analysis of why the redacted information is both (i) not material and (ii) would be competitively harmful if publicly disclosed.<sup>49</sup> Pursuant to Rule 83, registrants may request confidential treatment of this supplemental information while it is in the staff's possession. If the registrant's supplemental materials do not support its redactions, the staff may request that the registrant file an amendment that includes some, or all, of the previously redacted information, similar to the process the staff currently follows for confidential treatment requests under Rule 406 and Rule 24b-2. After completing its review of the supplemental materials, the Commission or its staff would return or destroy them at the request of the registrant if the registrant complies with the procedures outlined in Rule 418 under the Securities Act or Rule 12b-4 under the Exchange Act, as applicable.

### b. Comments

Many commenters favored this proposal.<sup>50</sup> Several commenters that supported the proposal stated that the current rules impose a significant burden on registrants and that reducing the significant cost and time expended to prepare and process confidential treatment requests would provide much needed relief without diminishing the quality of information available to

<sup>44</sup> See letters from BDO, CAQ, Cravath, E&Y, PricewaterhouseCoopers ("PWC"), and Sullivan.

<sup>45</sup> 5 U.S.C. 552 ("FOIA"). Rule 80 [17 CFR 200.80 *et seq.*], the Commission's rule adopted under FOIA, incorporates the criteria for permissible non-disclosure set forth in FOIA. Of the list of available FOIA disclosure exemptions provided in Section 552(b), most applicants for confidential treatment rely on paragraph (b)(4), which exempts certain trade secrets or privileged or confidential commercial or financial information.

<sup>46</sup> Exchange Act Rule 24b-2 and Securities Act 406 require that applicants for confidential treatment justify their nondisclosure on the basis of the applicable exemption(s) from disclosure under Rule 80.

<sup>47</sup> The Division has published procedural and substantive guidance on how to prepare and submit confidential treatment requests in Staff Legal Bulletins 1 and 1A, available on the Commission's website at <https://www.sec.gov/interps/legal/slbcf1.txt> and <https://www.sec.gov/interps/legal/slbcf1r.htm>.

<sup>48</sup> See Rule 12b-20 [17 CFR 240.12b-20], Rule 408(a) [17 CFR 230.408(a)], and proposed Item 601(b)(10)(iv).

<sup>49</sup> This analysis would be substantially the same as is currently required in confidential treatment requests.

<sup>50</sup> See, e.g., letters from Eversheds Sutherland (US) LLP, on behalf of the Committee of Annuity Insurers ("Comm. of Annuity Insurers"), CCMC, Cravath, Davis Polk, FedEx, Fenwick, Financial Executives, Grumman, IMA, Reed Smith LLP ("Reed Smith"), SIFMA, Society for Corp. Gov., and Sullivan (supporting the proposal). *But see*, letters from CII and Public Citizen (opposing the proposal).

investors.<sup>51</sup> Along these lines, commenters indicated the proposed revisions to Item 601(b)(10) would effectively change only the confidential treatment process, not the substance of registrants' disclosure.<sup>52</sup> For example, two commenters noted that published guidance, such as Staff Legal Bulletins 1 and 1A, is readily available to registrants and sets forth the staff's long established views on appropriate redactions of confidential information in accordance with Rules 406 and 24b-2.<sup>53</sup> Commenters also observed that the staff would retain the ability to review any of the information redacted by registrants from their filings, as necessary on a case-by-case basis. Several commenters noted that the prospect of staff review and request for further information would continue to act as a safeguard for investors, much as the staff's selective review process of filings generally operates today.<sup>54</sup>

However, not all commenters supported the proposal. In particular, two commenters expressed concern that if registrants were no longer required to formally request confidential treatment of redactions in their exhibits, they may be motivated to err on the side of redacting much more information than would likely be afforded confidential treatment under the current system.<sup>55</sup>

In the Proposing Release, the Commission asked whether to extend the proposal beyond Item 601 to reach:

- Exhibits required by other subsections of Item 601, including Item 601(b)(2);
- Exhibits required by certain of the Commission's disclosure forms to which the exhibit requirements of Item 601 do not specifically apply;<sup>56</sup> and
- Exhibits required by certain of the Commission's disclosure forms related to investment companies.<sup>57</sup>

Several commenters supported expanding the proposed accommodation to exhibits filed pursuant to Item 601(b)(2), which

requires registrants to file as exhibits any plans of acquisition, reorganization, arrangement, liquidation, or succession.<sup>58</sup> One such commenter stated that including Item 601(b)(2) within the coverage of the proposed amendments was a sensible approach given that Item 601(b)(2) exhibits are substantively a subset of 601(b)(10) exhibits. However, this commenter also suggested initially limiting the proposed amendments to Item 601(b)(2) and 601(b)(10) and revisiting potential expanded applicability at a future date.<sup>59</sup>

By contrast, a few commenters favored immediately expanding the proposal beyond 601(b)(2) and 601(b)(10), specifically to underwriting agreements required by Item 601(b)(1)<sup>60</sup> or generally to all exhibits filed pursuant to Item 601.<sup>61</sup> These commenters reasoned that, for purposes of the proposed rule change, there was no meaningful basis to distinguish these additional exhibits from material contracts filed under Item 601(b)(10). One such commenter noted that broadening the rule change to all Item 601 exhibits would promote a more consistent approach to confidential treatment overall.<sup>62</sup>

None of the commenters that supported the proposal objected to an analogous change to the exhibit requirements of Commission disclosure forms for which Item 601(b)(10) does not apply. In addition, two commenters recommended that the proposals should be expanded to provide similar accommodations to investment companies.<sup>63</sup>

#### c. Final Amendment

We are adopting the amendment to Item 601(b)(10) as proposed. We have, however, slightly revised the language of the amendment to refer to information that "would likely cause competitive harm" to more closely track the standard under FOIA.<sup>64</sup> In addition, we are amending Item 601(b)(2) in a similar manner to allow registrants to redact immaterial provisions or terms from agreements filed under that item that would likely cause them competitive harm if publicly disclosed.<sup>65</sup> To facilitate consistency

across our exhibit requirements, we are also expanding the proposal to certain exhibit related requirements in specified disclosure forms for which Item 601(b)(10) does not apply.<sup>66</sup>

We believe that these amendments will substantially reduce the burden currently borne by registrants in preparing and processing requests for confidential treatment while still providing all material information to investors. As such, we believe these amendments are in keeping with our mandate under the FAST Act. In our view, the sizeable costs to registrants, in terms of financial expenditures, staff time, and potential transactional delays resulting because of time spent on confidential treatment request applications, justifies such an approach where, as here, any corresponding negative impact on investors is expected to be minimal. The amendments to Item 601 do not substantively alter registrant disclosure requirements—they do not affect the principles of what a registrant may or may not permissibly redact from its disclosure for reasons of confidentiality, nor do they change the fundamental disclosure obligations a registrant owes its shareholders under the federal securities laws. Rather, the amendments recognize that the administrative process by which registrants currently are permitted to protect confidential information in certain exhibits is not the most efficient way to serve investors' interests. In response to commenters who expressed concern that registrants would err on the side of redacting much more information than would likely be afforded confidential treatment under the current system, we note that these procedural revisions do not limit the Commission or its staff's prerogative to scrutinize the appropriateness of a registrant's omissions of information from its exhibits. In this regard, we emphasize that the amended rules retain the requirement that exhibits be clearly marked to indicate where immaterial and competitively harmful information

to omit (i) schedules, appendices and attachments to exhibits that are not material and (ii) personally identifiable information are discussed *infra* at Section II.B.5.b.i. and ii.

<sup>66</sup> See amendments to Form 20-F (Instructions as to Exhibits), Form 8-K (Instructions 4-6 to Item 1.01), Form N-1A (new Instruction 4 to Item 28), Form N-2 (new Instruction 6 to Item 25.2), Form N-3 (new Instruction 5 to Item 29(b)), Form N-4 (new Instruction 5 to Item 24(b)), Form N-5 (new Instruction 3 of Instructions as to Exhibits), Form N-6 (new Instruction 3 to Item 26), Form N-14 (new Instruction 3 to Item 16), Form S-6 (new Additional Instruction 3 to the Instructions as to Exhibits), and Form N-8B-2 (new Instruction 3 to IX. Exhibits).

<sup>51</sup> See letters from Comm. of Annuity Insurers, Cravath, Davis Polk, FedEx, IMA, Reed Smith, Society for Corp. Gov., and Sullivan. See also letter from Reed Smith (stating that the current requirements for confidential treatment disproportionately burden smaller reporting companies).

<sup>52</sup> See, e.g., letters from Cravath, Davis Polk, and Society for Corp. Gov.

<sup>53</sup> See letters from Cravath and Davis Polk.

<sup>54</sup> See letters from Comm. of Annuity Insurers, Cravath, Fenwick, Reed Smith, SIFMA, and Society for Corp. Gov.

<sup>55</sup> See letters from CII and Public Citizen.

<sup>56</sup> For example, Form 20-F, for use by foreign private issuers, has its own exhibit requirements that do not reference Item 601 of Regulation S-K. See Item 19 of Form 20-F.

<sup>57</sup> See Proposing Release, *supra* note 5, Section II.E.2.c, at 51004.

<sup>58</sup> See letters from Cravath, Fenwick, SIFMA, and Sullivan.

<sup>59</sup> See letter from Cravath.

<sup>60</sup> See letter from SIFMA.

<sup>61</sup> See letter from Society for Corp. Gov.

<sup>62</sup> *Id.*

<sup>63</sup> See letters from Comm. of Annuity Issuers and Investment Company Institute ("ICI").

<sup>64</sup> See new paragraph (iv) to Item 601(b)(10).

<sup>65</sup> Additional amendments to the exhibit requirements of Item 601 that will allow registrants

has been omitted<sup>67</sup> and that any redactions will remain subject to review and comment at the staff's discretion.<sup>68</sup>

As noted, consistent with several commenters' suggestions, we are adopting revisions to Item 601(b)(2) that will conform to the treatment of exhibits in amended Item 601(b)(10). We agree with those commenters who stated that these exhibits are generally a subset of the material agreements filed under Item 601(b)(10) and should be treated the same way.

At this time, we are not expanding this approach to other exhibits required by Item 601, given the specialized subject matter and specific considerations relevant to each exhibit. For example, we believe it would be a very rare case that a company would appropriately be able to exclude portions of other exhibits such as the articles of incorporation, bylaws, legal or tax opinions, and codes of ethics. Moreover, by a significant margin, the vast majority of confidential treatment requests handled by the Commission is made in connection with exhibits filed pursuant to Item 601(b)(10).<sup>69</sup>

Finally, to facilitate the consistency of our exhibit requirements across different forms, we are adopting a parallel approach to information omitted from exhibits required by certain other forms and rules for which the exhibit requirements of Item 601 do not apply. For example, as we discuss below, we are adopting amendments to

Form 20-F<sup>70</sup> to maintain a consistent approach to the exhibit filing requirements for domestic registrants and foreign private issuers. We are also amending Item 1.01 of Form 8-K to conform to the revisions to Item 601(b)(10)(iv). Item 1.01 of Form 8-K requires the disclosure of material definitive agreements that are not made in the ordinary course of business. The item parallels Item 601(b)(10) of Regulation S-K with regard to the types of agreements that are material to a company, but it does not require that the material agreements themselves be filed as exhibits to the Form 8-K. In 2004, when Item 1.01 was added to Form 8-K, the Commission considered mandating an Item 1.01 exhibit filing requirement but ultimately chose not to do so after considering the views of commenters.<sup>71</sup> Commenters expressed concern that the short Form 8-K filing period would make it too difficult to prepare and submit requests for confidential treatment of sensitive terms of the agreements in a timely manner.<sup>72</sup> Instead, the Commission retained the rule that material agreements disclosed on Form 8-K do not need to be filed until the company's next periodic report or registration statement, but encouraged companies to file such agreements with the Form 8-K to the extent practicable.<sup>73</sup> Accordingly, although the language of Item 1.01 and its instructions reference Item 601(b)(10) of Regulation S-K for purposes of determining which agreements must be reported under this Form 8-K item, they do not specifically incorporate the exhibit filing requirements of Item 601(b)(10). We are therefore adopting changes to Form 8-K to clarify that the accommodations to the exhibit filing requirements extend to Item 1.01 of Form 8-K as well, to the extent such exhibits are filed with the intention of being incorporated into future filings in satisfaction of Item 601(b)(10).

For policy reasons similar to those described above, we are adopting parallel amendments to the registration forms used by investment companies to allow them to redact immaterial provisions or terms from exhibits filed as "other material contracts" that would likely cause the registrant competitive

harm if publicly disclosed.<sup>74</sup> We are also extending this treatment to information in reinsurance agreements required to be filed as exhibits under Forms N-3, N-4, and N-6.<sup>75</sup> Staff of the Division of Investment Management has routinely granted confidential treatment as to information in reinsurance agreements in the past. We believe that extending this relief to these specific categories of exhibits will substantially reduce the burden currently borne by registrants in preparing and processing requests for confidential treatment, while still providing all material information to investors holding those contracts.

### 3. Financial Statements: Incorporation by Reference and Cross-Reference of Information<sup>76</sup>

#### a. Proposed Amendments

Having financial statements cross-reference to disclosure in other parts of a filing or incorporate information by reference from other filings can raise questions as to the scope of an auditor's responsibilities.<sup>77</sup> To address this concern, the Commission proposed amendments to our rules and forms that would prohibit such incorporation by reference or cross-referencing.<sup>78</sup> The proposed amendments did not, however, prohibit cross-references to other parts of a filing when otherwise specifically permitted by our rules. The proposed amendments also did not prohibit incorporating financial

<sup>67</sup> Both Item 601(b)(2)(ii) and new Item 601(b)(10)(iv) require the registrant to mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

<sup>68</sup> Where applicable, the staff may request that a registrant file an amendment that includes some, or all, of the information previously redacted from an exhibit. We note that the rule, as revised, does not require a registrant to include an explanatory note in its amendment describing why the amendment was necessary. In the Proposing Release, the Commission asked whether it should impose such a requirement. No commenters advocated in favor of such a requirement and, after consideration, we do not think it necessary. This is consistent with the Commission's approach to filing amendments generally, whereby registrants are not required to annotate their changes to documents. We also are mindful that such explanations could, by drawing the attention of the reader, overemphasize the importance of the amended information. See letters from Reed Smith and Society for Corp. Gov.

<sup>69</sup> For example, in the fiscal year ended 2018, out of 1,239 requests for confidential treatment 1,130 related to exhibits filed pursuant to Item 601(b)(10). Similarly, of the 1,188 CTRs granted by the Commission that year, 1,086 related to exhibits filed pursuant to Item 601(b)(10).

<sup>70</sup> Unlike the exhibit requirements of Form 20-F, which are separate from and do not reference Item 601 of Regulation S-K, the registration statement Forms F-1, F-3, F-4 for foreign private issuers all require registrants to comply with the exhibit requirements of Item 601.

<sup>71</sup> See *Additional Form 8-K Disclosure Requirements and Acceleration of Filing Date*, Release No. 33-8400 (Mar. 16, 2004) [69 FR 15593] ("2004 8-K Release"), at 15996-7.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 15597.

<sup>74</sup> See new Instruction 4 to Item 28 of Form N-1A; new Instruction 6 to Item 25.2 of Form N-2; new Instruction 5 to Item 29(b) of Form N-3; new Instruction 5 to Item 24(b) of Form N-4; new Instruction 3 of Instructions as to Exhibits of Form N-5; new Instruction 3 to Item 26 of Form N-6; new Instruction 3 to Item 16 of Form N-14; new Additional Instruction 3 to the Instructions as to Exhibits of Form S-6; and new Instruction 3 to IX. Exhibits of Form N-8B-2.

<sup>75</sup> See new Instruction 5 to Item 29(b) of Form N-3, new Instruction 5 to Item 24(b) of Form N-4, and new Instruction 3 to Item 26 of Form N-6. Reinsurance agreements are required to be filed as separate and distinct exhibits within the list of exhibit items required by Forms N-3, N-4, and N-6. Registrants often seek confidential treatment of the negotiated terms and of proprietary information about how they operate their insurance business that is included in these agreements.

<sup>76</sup> For a discussion of other amendments we are adopting that also pertain to our rules regarding incorporation by reference, see Section II.B.6 *infra*.

<sup>77</sup> See Proposing Release, *supra* note 5, Section II.F.2.c. at 51010.

<sup>78</sup> The Commission proposed amendments to Rule 411, Rule 12b-23, and Rule 0-4 and Securities Act Forms S-1, S-3, S-11, and F-1. Because Rule 0-6 governs incorporation by reference only for applications filed under the Investment Advisers Act, the Commission did not propose to make similar amendments to that rule, but did request comment on whether the final amendments should include this provision. We received no comments regarding extending similar amendments to Rule 0-6.

information from other filings to satisfy financial reporting requirements when otherwise permitted or required.<sup>79</sup> In addition, for consistency with both current and proposed Rule 411 and Rule 12b-23, we also proposed an additional amendment to Rule 0-4 providing restrictions on the incorporation of financial information required to be given in comparative form for two or more fiscal years or periods.<sup>80</sup>

#### b. Comments

Several commenters supported the proposed amendments,<sup>81</sup> while one commenter opposed.<sup>82</sup> Although this commenter shared the concern over the need to define the scope of the auditor's responsibilities, it stated that prohibiting incorporation by reference or cross-referencing of information into the financial statements was a significant lost opportunity to improve the delivery of information to investors by improving the technology platform on which the Commission collects and disseminates that information. A number of commenters suggested that the final rule permit foreign private issuers on Form 20-F to cross-reference outside the financial statements when expressly permitted by applicable accounting standards, such as IFRS or by law, regulation or by the primary securities regulator in the registrant's home country jurisdiction or market.<sup>83</sup> A few commenters requested confirmation that the proposal would not affect financial reporting for certain investment company "fund of funds" arrangements, such as a master/feeder arrangement.<sup>84</sup>

<sup>79</sup> For example, registrants using Form S-3 would continue to be permitted to incorporate financial statements filed with a Form 8-K that reports the acquisition of a significant business. Also, registrants using Form S-4 to report a merger with another registrant would continue to be able to incorporate the financial statements of the registrant filed on Form 10-K and Form 10-Q. Similarly, investment company registrants using, for example, Form N-1A would continue to be permitted to incorporate financial statements included as part of reports to shareholders that are filed on Form N-CSR.

<sup>80</sup> See proposed Rule 0-4(b).

<sup>81</sup> See letters from BDO, CAQ, Deloitte, E&Y, Grant Thornton LLP ("Grant Thornton"), Pricy Bowler, PWC, and ICL.

<sup>82</sup> See letter from Sullivan.

<sup>83</sup> See letters from CAQ, Deloitte, E&Y, KPMG, and PWC.

<sup>84</sup> See letters from CAQ, KPMG, and PWC. Feeder funds typically invest their assets solely in another investment company (a master fund), and provide financial statements of the master fund together with the feeder fund's financial statements. Generally, the staff of the Division of Investment Management has taken the position that the financial presentation that is most meaningful in the feeder fund context is unconsolidated, provided that, among other things, the feeder fund attaches the financial statements of the master fund to its

#### c. Final Amendments

We are adopting the amendments as proposed, with the following modification. In response to commenters who were concerned that the proposed amendments may create uncertainty regarding cross-references and incorporation by reference in the financial statements when expressly permitted by applicable accounting standards, such as IFRS, our amendments explicitly provide that incorporating by reference, or cross-referencing to, information outside of the financial statements is not permitted unless otherwise specifically permitted or required by the Commission's rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.<sup>85</sup>

While the use of cross-references and incorporation by reference to present information can help investors access information, navigate disclosure and focus on key information, we believe it is necessary to place restrictions on the ability of registrants to cross-reference and incorporate by reference information into the financial statements. By generally prohibiting this practice, with certain exceptions as noted above, the amendments address concerns that referencing information outside the audited financial statements to satisfy financial statement disclosure requirements could create confusion about which financial information has been audited or reviewed by the independent auditor.<sup>86</sup> We think these changes will reduce potential confusion and make it less cumbersome for investors to determine what pieces of financial information form a set of audited or reviewed financial statements. While we appreciate the views of the commenter who opposed the amendments on the grounds that they represented a missed opportunity to improve the technology platform on which the Commission collects and disseminates information to investors,

financial statements. See Investment Management Guidance Update No. 2014-11, Investment Company Consolidation, available at <http://www.sec.gov/investment/imguidance-2014-11.pdf>; and SEC Staff Generic Comment Letter for Investment Company CFOs (Dec. 30, 1998), available at <https://www.sec.gov/divisions/investment/imlr1230.htm>. The amendments we are adopting today would not change the staff interpretation that the master fund's financial statements should be attached to the feeder fund's financial statements and not incorporated by reference.

<sup>85</sup> See, as amended, Rule 411, Rule 12b-23, Rule 0-4, and Forms S-1, S-3, S-11, and F-1.

<sup>86</sup> See letter from Deloitte.

broader changes to the Commission's EDGAR system are outside the scope of this rulemaking and we do not agree that adoption of this change would precondition the Commission's approach in any future technology changes.

#### B. Adoption of Amendments as Proposed

##### 1. Description of Property (Item 102)

###### a. Proposed Amendments

Item 102 of Regulation S-K requires that registrants disclose "the location and general character of the principal plants, mines, and other materially important physical properties of the registrant and its subsidiaries." The instructions to Item 102 further clarify the type of information required, specifying that registrants:

- Must disclose such information as reasonably will inform investors as to the suitability, adequacy, productive capacity, and extent of the registrant's utilization of the facilities;<sup>87</sup> and
- should take into account both quantitative and qualitative factors when determining whether properties should be described.<sup>88</sup>

Despite existing language in Item 102 that limits the required information to properties that are "materially important" to the registrant and its subsidiaries, the disclosure elicited in response to this item may not have been consistently material.<sup>89</sup> For many companies, the only physical properties held may be their headquarters, office space, or ancillary facilities, a description of which is likely to be unimportant to an investor's evaluation of an investment in the company. Even where a description of the registrant's physical properties is more likely to be salient to investors, such as with manufacturing companies, data centers,

<sup>87</sup> See Instruction 1 to Item 102 of Regulation S-K. Detailed descriptions of the physical characteristics of individual properties or legal descriptions by metes and bounds are not required.

<sup>88</sup> See Instruction 2 to Item 102 of Regulation S-K. Disclosure specific to the mining, oil and gas, and real estate industries is outside the scope of this rulemaking. Instruction 3 of Item 102 applies to the mining industry. The Commission has separately adopted revisions to the property disclosure requirements for mining registrants. See *Modernization of Property Disclosures for Mining Registrants*, Release No. 33-10570 (Oct. 31, 2018) [83 FR 66344 (Dec. 26, 2018)] ("Modernization for Mining Registrants Release"). Instructions 4, 5, and 6 of Item 102 apply to the oil and gas industry. The Commission considered disclosure specific to the oil and gas industry in 2008. See *Modernization of Oil and Gas Reporting*, Release No. 33-8995 (Dec. 31, 2008) [74 FR 2158 (Jan. 14, 2009)]. Instruction 9 of Item 102 applies to the real estate industry.

<sup>89</sup> See the Proposing Release, *supra* note 5, at nn. 21 through 23 and see generally Section II.A. of the Proposing Release, *supra* note 5. See also Fast Act Report, *supra* note 7, at Section IV.B.1, and Concept Release, *supra* note 9, at Section IV.A.6.b.

or casinos, the language of Item 102 may not provide sufficient clarity to registrants for determining which of their properties must be described. For example, commenters have pointed out that Item 102 contains a mixture of different disclosure triggers, such as references to “principal” plants and mines, “materially important” physical properties, and “major” encumbrances, which together in the same disclosure requirement may create unnecessary ambiguity.<sup>90</sup> In addition, while Instruction 2 of Item 102 incorporates the materiality concepts of Instruction 1 to Item 101 of Regulation S–K, Instruction 1 of Item 102 provides no such materiality overlay. This lack of harmony in Item 102 has created uncertainty about the scope of the rule and has likely contributed to the disclosure of immaterial information.

To address this issue, the Commission proposed revising Item 102 to emphasize materiality, which was consistent with several commenters’ suggestions and the staff’s recommendation in the FAST Act Report.<sup>91</sup> The Commission proposed to amend Item 102 to require disclosure to the extent physical properties are material to the registrant, which would include those properties that are material to the registrant’s business.<sup>92</sup> The proposal was also intended to harmonize the various non-industry-specific triggers<sup>93</sup> for disclosure in Item 102 by replacing them with a consistent materiality threshold that would facilitate its application. The Commission also proposed to clarify that the disclosure required under Item 102 may be provided on a collective basis, if appropriate.

<sup>90</sup> See Section II.A. of the Proposing Release, *supra* note 5, and note 28 of that release (citing to the American Bar Association’s comment letter of March 6, 2015 with respect to the Commission’s Disclosure Effectiveness initiative).

<sup>91</sup> See FAST Act Report, *supra* note 7, at Recommendation B.1.

<sup>92</sup> In the Proposing Release, the Commission stated the belief that this approach would not inadvertently omit disclosures that would be material to the registrant, but not its ongoing business, such as properties that have value that is material to the registrant but are no longer important to its operations. See Proposing Release, *supra* note 5, Section II.A., at 50991.

<sup>93</sup> In light of the particular significance of this disclosure for registrants in the mining, real estate, and oil and gas industries, the Commission did not propose to modify any of the instructions of Item 102 specific to those industries. Instructions 3 through 7 to Item 102 are industry-specific. For example, Instruction 3 of Item 102 requires that registrants engaged in mining operations must refer to, and if required, provide the disclosure under §§ 229.1300 through 229.1305 (subpart 1300) of Regulation S–K, in addition to any disclosure required by Item 102. See *supra* note 88.

#### b. Comments

Many commenters supported the proposal to focus the required disclosure on material physical properties, with several of these commenters stating that the proposed amendments would help reduce unnecessary disclosure.<sup>94</sup> Several commenters suggested different formulations of the rule. For example, one commenter recommended that Item 102 be subsumed into the disclosure objectives of Item 101 and specific references to “material” and “materiality” in the item be omitted in favor of a more precisely articulated disclosure objective.<sup>95</sup> Another commenter suggested that the rule require disclosure only of properties that present specific risks to the registrant, which might mitigate the use of boilerplate disclosure.<sup>96</sup> A third commenter supported the proposed amendment but recommended that it apply uniformly to all issuers regardless of industry, including the real estate and extractive industries.<sup>97</sup>

In the Proposing Release, the Commission also requested comment on whether to further amend Item 102 to require additional disclosure about material properties, such as uncertainties in connection with these properties. A number of commenters responded that requiring such additional disclosure would only duplicate existing requirements, such as those in Items 101, 103, 303, and 503(c) of Regulation S–K and Exchange Act

<sup>94</sup> See letters from American Fuel (supporting the revision because it “would help reduce disclosure of immaterial information and therefore alleviate the possibility of disclosure overload”), Business Roundtable (stating generally that a focus on materiality “helps filter unnecessary information out of disclosures, providing investors a clearer picture of a company’s business and financial profile”) and Cravath (stating that the proposed amendments “should enhance [Item 102] disclosure where appropriate or eliminate it where not material”), CCMC, CNA, Davis Polk, E&Y, FedEx, Fenwick, Financial Executives, Grumman, IMA, Lark Research, Nasdaq, Reed Smith, SIFMA, Society for Corp. Gov., and Sullivan.

<sup>95</sup> See letter from E&Y, recommending that the disclosure objective for properties should be “to identify assets that contribute significantly to enterprise value, that are unique or provide competitive advantage, that could not be readily replaced or that present a significant risk to the enterprise if the registrant loses [its] use or access to them.”

<sup>96</sup> See letter from IMA (providing as an example the risk of expropriation of an oil and gas facility by an unstable government).

<sup>97</sup> See letter from CCMC (acknowledging that while physical properties will often be material to companies in the real estate and extractive industries, there are many situations where individual properties or groups of related properties are not material to particular issuers in these industries).

Rule 12b–20, as well as the financial statement footnotes.<sup>98</sup>

Finally, some commenters favored removing Item 102 as a separate disclosure item and incorporating it into the description of business required by Item 101,<sup>99</sup> an approach that the staff previously put forward in the FAST Act Report.<sup>100</sup>

#### c. Final Amendment

We are adopting the amendment to Item 102 as proposed.<sup>101</sup> The revised item makes clear that, unless otherwise specified, disclosure need only be provided about a physical property to the extent that it is material to the registrant. The final rules provide a uniform standard of disclosure based on materiality for non-industry specific properties. Because determinations of materiality are fact-specific and encompass a wide range of possible considerations, we do not think it is appropriate to further limit the criteria for Item 102 disclosure by focusing only on certain specific risks or other narrowly defined measures of materiality. We believe that registrants are best suited to determine which, if any, of their physical properties warrant discussion based on what is material to them in light of their particular circumstances. Under this approach, some physical properties held by a registrant may not be material. In some cases, application of this analysis may result in a description of property on an individual basis or on a collective basis, or may result in no disclosure.

We have not modified any of the instructions to Item 102 that relate to specific industries. As stated in the Proposing Release, the particular significance and unique considerations of property disclosure for registrants in the mining, real estate, and oil and gas industries weigh in favor of separate consideration.<sup>102</sup>

We are also not opting to combine Item 102 with Item 101, as some commenters recommended. We continue to believe any effort to combine these requirements should be in the context of a broader inquiry into the purpose and function of a registrant’s disclosure of its business operations, which was outside of the scope of this rulemaking.

<sup>98</sup> See letters from American Fuel, Cravath, Davis Polk, Fenwick, Reed Smith, SIFMA, Society for Corp. Gov., and Sullivan.

<sup>99</sup> See letters from E&Y and Sullivan.

<sup>100</sup> See letters from E&Y and Sullivan. See also FAST Act Report, *supra* note 7, at Recommendation B.1.

<sup>101</sup> See revised Item 102.

<sup>102</sup> See *supra* note 88, noting that the Commission has separately adopted revisions to the property disclosure requirements for mining registrants.

## 2. Management, Security Holders, and Corporate Governance

### a. Amendment to Item 401 of Regulation S-K (Directors, Executive Officers, Promoters, and Control Persons)

Item 401 of Regulation S-K sets forth disclosure requirements about the identity and background information of a registrant's directors, executive officers, and significant employees.<sup>103</sup> Form 10-K, which is one of several forms that calls for such disclosure, allows registrants to incorporate this information (and all other information required by Part III of Form 10-K) by reference to their definitive proxy or information statement.<sup>104</sup> As an alternative to incorporating this information by reference to a definitive proxy or information statement, Instruction 3 to Item 401(b) allows registrants to include required information about their executive officers in Part I of Form 10-K. If a registrant chooses this alternative, Instruction 3 states that the registrant is not required to repeat that information in its definitive proxy or information statement.

To make clear that Instruction 3 applies to any executive officer disclosure required by Item 401, and therefore registrants need not duplicate such disclosure in their definitive proxy or information statement if they have already provided it in their Form 10-K, the Commission proposed to clarify the scope of the instruction by moving it from Item 401(b) and making it a general instruction to Item 401. The Commission also proposed to revise the required caption for the disclosure if it is included in Part I of Form 10-K to reflect a "plain English" approach. The required caption would be "Information

<sup>103</sup> Item 401 was adopted in 1982 as part of the Commission's integrated disclosure initiative, although similar requirements can be traced back to Schedule A of the Securities Act. See *Adoption of Integrated Disclosure System*, Release No. 33-6383 (Mar. 3, 1982) [47 FR 11380 (Mar. 16, 1982)] (the "Integrated Disclosure System Adopting Release"). See also Securities Act, Schedule A, Paragraph 4 [15 U.S.C. 77aa(4)].

<sup>104</sup> General Instruction G.3 of Form 10-K. This instruction allows the information required by Item 401, along with other items required by Part III of Form 10-K, to be incorporated by reference from the registrant's definitive proxy or information statement (prepared in accordance with Schedule 14A) if the statement is filed with the Commission within 120 days after the end of the fiscal year covered by the Form 10-K. If the definitive proxy statement or information statement is not filed within the 120-day period or is not required to be filed with the Commission, the Part III information must be filed as part of the Form 10-K, or an amended Form 10-K, no later than the end of the 120-day period.

about our Executive Officers" instead of "Executive officers of the registrant."

Several commenters supported the amendments to Item 401 as proposed, and no commenters opposed.<sup>105</sup> One commenter suggested further expanding the instruction in Item 401 to allow registrants to omit additional disclosure from their definitive proxy or information statement if the disclosure was previously filed on Form 10-K.<sup>106</sup>

We are adopting the amendment to Item 401, as proposed, to eliminate any confusion arising from the current location of the instruction.<sup>107</sup> We are not expanding this amendment to cover other Part III disclosure about executive officers, such as Item 404 disclosure about related-party transactions, because doing so could result in bifurcating Part III disclosure between the Form 10-K and a separate proxy or information statement based on whether a party is an executive officer of the registrant. We think it is preferable to have the disclosure required by the Item in one filing.

### b. Compliance With Section 16(a) of the Exchange Act (Item 405)

Section 16(a) of the Exchange Act requires officers, directors, and specified types of security holders to report their beneficial ownership of a registrant's equity securities using forms prescribed by the Commission,<sup>108</sup> which must be filed electronically on EDGAR.<sup>109</sup> Item 405 requires registrants to disclose each reporting person<sup>110</sup>

<sup>105</sup> See letters from CCMC, Cravath, FedEx, Fenwick, Nasdaq, and Society for Corp. Gov.

<sup>106</sup> See letter from Cravath (regarding previously filed Item 404 disclosure). *But see* letter from Society for Corp. Gov. (arguing against expanding the instruction to Item 404 and other disclosure items relating to executive officers).

<sup>107</sup> New Instruction to Item 401 of Regulation S-K.

<sup>108</sup> See Form 3, Form 4, and Form 5.

<sup>109</sup> Reporting persons have been required to file their Section 16 reports on EDGAR since 2003. See *Mandated Electronic Filing and website Posting for Forms 3, 4 and 5*, Release No. 33-8230 (May 7, 2003) [68 FR 25788 (May 13, 2003)] ("Section 16 Mandatory Electronic Filing Release"). In addition, all registrants who maintain a corporate website are required to post any Section 16 reports relating to the equity securities of the registrant on such website pursuant to Rule 16a-3(k) of the Exchange Act [17 CFR 240.16a-3(k)], and many registrants satisfy this requirement by providing hyperlinks directly to the electronic filings once they are made on EDGAR. The Commission has noted that any concerns a registrant may have about obtaining an electronic copy of the filing from a Section 16 reporting person in order to satisfy the web posting requirement "would not arise for issuers that rely on a hyperlink (for example, to EDGAR) instead of, or in addition to, direct website posting." *Id.* at 25790.

<sup>110</sup> Item 405(a)(1) of Regulation S-K [17 CFR 229.405(a)(1)] defines a "reporting person" as "each

who failed to file Section 16 reports on a timely basis during the most recent fiscal year or prior fiscal years.<sup>111</sup> The disclosure is required under the caption "Section 16(a) Beneficial Ownership Reporting Compliance." Rule 16a-3(e) currently requires reporting persons to furnish a duplicate of those Section 16 reports to the registrant.<sup>112</sup> Registrants are instructed under Item 405(a) to provide the required disclosure relying solely on their review of such furnished reports and any written representation provided by such persons that no Form 5 is required.<sup>113</sup>

As described in the Proposing Release, the Commission proposed the following changes:<sup>114</sup>

- Eliminate the requirement in Rule 16a-3(e) that reporting persons furnish Section 16 reports to the registrant.
- Amend Item 405 to:
  - Clarify that registrants may, but are not required, to rely only on Section 16 reports that have been filed on EDGAR (as well as any written representations from the reporting persons) to assess whether there are any Section 16 delinquencies to disclose.<sup>115</sup>
  - Change the disclosure heading required by Item 405(a)(1) from "Section 16(a) Beneficial Ownership Reporting Compliance" to the more specific "Delinquent Section 16(a) Reports" and encourage registrants to exclude this heading altogether when they have no Section 16(a) delinquencies to report.

person who, at any time during the fiscal year, was a director, officer, beneficial owner of more than ten percent of any class of equity securities of the registrant registered pursuant to Section 12 of the Exchange Act, or any other person subject to Section 16 of the Exchange Act with respect to the registrant because of the requirements of Section 30 of the Investment Company Act."

<sup>111</sup> Item 405 was initially proposed in 1988 in an attempt to reduce the high delinquency rate for Section 16 reports. See *Ownership Reports and Trading by Officers, Directors and Principal Stockholders*, Release No. 34-26333 (Dec. 2, 1988) [53 FR 49997 (Dec. 13, 1988)] and *Ownership Reports and Trading by Officers, Directors and Principal Security Holders*, Release No. 34-27148 (Aug. 18, 1989) [54 FR 35667 (Aug. 29, 1989)] (reproposing Item 405 in response to comments on the 1988 proposing release).

<sup>112</sup> See 17 CFR 240.16a-3(e).

<sup>113</sup> See Item 405(a) and (b)(1).

<sup>114</sup> See Proposing Release, *supra* note 5, Section I.C.2 at 50995-6. These proposed amendments were based on staff recommendations in the FAST Act Report, which called for revisions to Item 405 and Rule 16a-3(e) in light of the availability of Section 16 reports on EDGAR. See FAST Act Report, *supra* note 7, at Recommendation D.2. See also Section 16 Mandatory Electronic Filing Release, *supra* note 109, at 25790.

<sup>115</sup> Proposed Item 405(b).

• Eliminate the checkbox on the cover page of Form 10-K (and the related instruction in Item 10 of Form 10-K) whereby the registrant indicates that there is no disclosure of delinquent filers in the Form 10-K and, to the best of the registrant's knowledge, will not be included in a definitive proxy or information statement incorporated by reference.

We received several comments on the proposed amendments,<sup>116</sup> all of which generally supported the revisions, with some commenters recommending slight modifications to the rules as proposed.<sup>117</sup>

We are adopting the amendments to Item 405, Section 16a-3(e), and the cover page of Form 10-K, as proposed. We believe these amendments, taken together, will improve the Section 16 disclosure regime for the benefit of both registrants and investors by making the rules more straightforward, compliance less burdensome, and the disclosure itself more streamlined.

Rule 405, as amended, will allow registrants to leverage the availability of Section 16 reports on EDGAR to perform their diligence for Item 405 disclosures more efficiently and with a greater degree of confidence in the results.<sup>118</sup> By shifting the focus of a registrant's inquiry to Section 16 reports filed electronically on EDGAR, revised Item 405 modernizes and simplifies the registrant's compliance with Item 405 while still providing all material information. However, registrants are not restricted to only these documents and may, but are not required, to expand the scope of their inquiry.<sup>119</sup>

<sup>116</sup> See letters from CCMC, Cravath, FedEx, Fenwick, and Society for Corp. Gov.

<sup>117</sup> See letter from Society for Corp. Gov. (suggesting that changing the caption to "Delinquent Section 16(a) Reports" was unnecessary) and letter from Cravath (suggesting that there may be some value in requiring affiliates, other than officers and directors, to provide registrants with electronic notice of delinquent Section 16 reports).

<sup>118</sup> See revised Item 405(b) [17 CFR 229.405(b)]. Revised Item 405(b) permits registrants to rely on a review of Section reports filed electronically with the Commission during the registrant's most recent fiscal year and any written representations from reporting persons that no Form 5 is required.

<sup>119</sup> Item 405 previously provided that the registrant "shall" make its disclosure "based solely upon" the Section 16 reports furnished to it pursuant to Rule 16a-3(e) and any written representation from a reporting person that no Form 5 is required. As stated in the Proposing Release, this language could be read to suggest that registrants may not rely on information outside of the Section 16 reports furnished to the registrant pursuant to Rule 16a-3(e). Therefore, revised Item 405(b) provides that registrants "may" rely only on the Section 16 reports and the written representation. As a result, if a registrant were aware that information in a Section 16 report submitted on EDGAR was not complete or accurate,

Consistent with this shift away from furnished reports, as proposed, we are also removing the provision in Rule 16a-3(e) that requires Section 16 reporting persons to provide a duplicate copy of their reports to the registrant. This provision, which predates EDGAR and the requirement that all reporting persons electronically file their Section 16 reports, has become unnecessary.<sup>120</sup>

We are also changing the required caption in Item 405(a)(1) from "Section 16(a) Beneficial Ownership Reporting Compliance" to "Delinquent Section 16(a) Reports" and including an instruction to this item to clarify that registrants are encouraged not to provide this caption if there are no delinquencies to report, as proposed. This revision is intended to minimize unnecessary disclosure and, at the same time, facilitate the ability of investors to identify and monitor Section 16 delinquencies.

Finally, we are modifying the cover page of Form 10-K, as proposed, to eliminate the checkbox indicating the absence of Item 405 disclosure in a registrant's Form 10-K and its definitive proxy or information statement incorporated by reference. We believe the value of this cover page disclosure has outlived its usefulness as a tool to facilitate the staff's processing and review of the form.<sup>121</sup>

### 3. Corporate Governance (Item 407)

Several disclosure requirements related to corporate governance are consolidated in Item 407.<sup>122</sup> The Commission proposed amendments to update a reference to an outdated auditing standard in Item 407(d)(3)(i)(B) and proposed to revise Item 407(e)(5) to clarify that emerging growth companies ("EGCs") are not required to provide a compensation committee report.<sup>123</sup> We are adopting these amendments as proposed, as further discussed below.

or that a reporting person failed to file a required report, it could provide appropriate disclosure pursuant to Item 405, as revised. See Proposing Release, *supra* note 5, at 50995.

<sup>120</sup> For the same reason, we are not amending our rules to require that reporting persons provide notice to the registrant when they file a Section 16 report on EDGAR. We believe such a notice requirement is not only unnecessary, but contrary to the objectives of this rulemaking to streamline our disclosure rules and make them less burdensome.

<sup>121</sup> See Proposing Release, *supra* note 5, Section II.C.2 at 50995-6.

<sup>122</sup> 17 CFR 229.407. Item 407 was adopted in 2006 to consolidate various corporate governance requirements under a single disclosure item. See *Executive Compensation and Related Person Disclosure*, Release No. 33-8732A (Aug. 29, 2006) [71 FR 53158 (Sept. 8, 2006)].

<sup>123</sup> See FAST Act Report, *supra* note 7, at Recommendations D.4 and D.5.

#### a. Audit Committee Discussions With Independent Auditor (Item 407(d)(3)(i)(B))

Under existing Item 407(d)(3)(i)(B), when a registrant files a proxy or information statement relating to an annual or special meeting of security holders at which directors are elected or written consents are provided in lieu of a meeting, a registrant's audit committee must state whether it has discussed with the independent auditor the matters required by AU section 380, *Communication with Audit Committees* ("AU sec. 380").<sup>124</sup> As described in the Proposing Release, the reference to AU sec. 380 has become outdated.<sup>125</sup> As such, the Commission proposed to update the reference to AU sec. 380 in Item 407(d)(3)(i)(B) by referring more broadly to "the applicable requirements of" the Public Company Accounting Oversight Board ("PCAOB") and the Commission.<sup>126</sup> Several commenters supported the proposed amendments, and no commenters opposed.<sup>127</sup> We are therefore adopting the amendments to Item 407(d)(3)(i)(B) as proposed. We believe this language will more easily accommodate any future changes to audit committee communication requirements.

#### b. Compensation Committee Report (Item 407(e)(5))

Item 407(e)(5)<sup>128</sup> requires a registrant's compensation committee to state whether it has reviewed and discussed the Compensation Discussion and Analysis ("CD&A") required by Item 402(b).<sup>129</sup> Based on this review and discussion, Item 407(e)(5) requires that the compensation committee state whether it recommended to the board of directors that the CD&A be included in the registrant's annual report, proxy statement, or information statement. The Commission proposed to amend

<sup>124</sup> See Instruction 3 to Item 407(d) of Regulation S-K.

<sup>125</sup> See Proposing Release, *supra* note 5, Section II.C.3.a. at 50996.

<sup>126</sup> See Auditing Standard No. 1301, *Communications with Audit Committees* ("AS 1301"), including Appendix B to AS 1301; Section 10A(k) of the Exchange Act [15 U.S.C. 78j-1(k)]; Rule 2-07 of Regulation S-X [17 CFR 210.2-07]; and Exchange Act Rule 10A-3 [17 CFR 240.10A-3].

<sup>127</sup> See letters from BDO, CAQ, CCMC, Cravath, Deloitte, E&Y, FedEx, Fenwick, Nasdaq, PWC, Society for Corp. Gov., and Sullivan. Two of these commenters also encouraged the staff to publish guidance that catalogs the specific PCAOB and Commission rules that are covered by revised Item 407(d)(3)(i)(B) at the time to avoid confusion and provide clarity to registrants. See letters from Cravath and Society for Corp. Gov. The staff will consider the necessity of such additional guidance.

<sup>128</sup> 17 CFR 229.407(e)(5).

<sup>129</sup> 17 CFR 229.402(b).

Item 407 to explicitly exclude EGCs from the Item 407(e)(5) requirement because they are not subject to a requirement to include a CD&A in their public disclosures.<sup>130</sup> Specifically, the proposed amendment added a reference to EGCs in Item 407(g), which currently excludes smaller reporting companies from Item 407(e)(5), among other provisions of Item 407. Several commenters supported the proposed amendments, and no commenters opposed.<sup>131</sup> Accordingly, we are adopting the amendments to Item 407(e)(5) as proposed.

#### 4. Registration Statement and Prospectus Provisions

##### a. Outside Front Cover Page of the Prospectus (Item 501(b))

Item 501(b)<sup>132</sup> sets forth disclosure requirements related to the outside front cover page of prospectuses.<sup>133</sup> The proposed amendments were intended to streamline these requirements and to provide registrants with greater flexibility in designing a cover page tailored to their business and the particular offering. We are adopting these amendments as proposed, as discussed below.

##### i. Name (Item 501(b)(1))

Item 501(b)(1) requires disclosure of a registrant's name, including an English translation of the name of foreign registrants. The instruction to Item 501(b)(1) states that if a registrant's name is the same as that of a "well known" company, or if the name leads to a misleading inference about the registrant's line of business, the registrant must include information to eliminate any possible confusion with the other company. If disclosure is insufficient to eliminate the confusion, the instruction indicates that the registrant may be required to change its name. The instruction provides an exception, however, if the registrant is an "established company," the character of the registrant's business has changed, and the "investing public is generally aware of the change and the character of [the registrant's] current business."<sup>134</sup>

<sup>130</sup> See Item 402(l) of Regulation S-K.

<sup>131</sup> See letters from CAQ, Cravath, FedEx, Fenwick, Nasdaq, Society for Corp. Gov., and CCMC.

<sup>132</sup> 17 CFR 229.501(b).

<sup>133</sup> See FAST Act Report, *supra* note 7, at Recommendations E.1-5.

<sup>134</sup> This policy reflected in Item 501(b)(1) with regard to misleading company names was first articulated by the Commission in 1969 in response to an increase in the number of registrants using names that the staff considered to be misleading. At the time, the Commission noted that registrants were using words such as "nuclear," "missile," "space," "nucleonics," and "electronics" in their

As discussed in the Proposing Release, in an effort to streamline Item 501(b)(1), the Commission proposed to eliminate the portion of the instruction to Item 501(b) that discusses when a name change may be required and the exception to that requirement.<sup>135</sup>

A few commenters supported the proposed amendment to Instruction 1 of Item 501(b)(1),<sup>136</sup> while some opposed it.<sup>137</sup> One commenter encouraged the Commission to eliminate the language about a registrant being required to change its name because this subject matter is already addressed by state law, as well as common law and federal trademark law.<sup>138</sup> The commenter asserted that the Commission's resources should not be devoted to matters "outside its core mission of investor protection that are already addressed by other regulators and non-securities laws."<sup>139</sup> However, one of the commenters who objected to the proposal stated that the Commission should be developing and expanding guidance on misleading names, not reducing it, noting that this issue continues to raise investor protection concerns.<sup>140</sup>

After considering these comments, we have decided to adopt the amendment as proposed. Our intent is to streamline the instruction to Item 501(b) in accordance with the objectives of this rulemaking to modernize and simplify our disclosure requirements, not to signal a change in Commission policy with respect to the use of potentially misleading company names. We continue to believe that a registrant's name could mislead investors under some circumstances. However, these situations can typically be addressed by the addition of clarifying disclosure and exercise of the Commission's discretion to take registration statements effective commensurate with the public interest and the protection of investors.<sup>141</sup>

names when they were not engaged in activity normally associated with those words, or were engaged to a limited extent. See *Guide for Preparation and Filing of Registration Statements; Misleading Names of Registrants*, Release No. 33-4959 (Apr. 16, 1969) [34 FR 6575 (Apr. 17, 1969)]. This policy was contained in Guide 53 of the Commission's Guides for Preparation and Filing of Registration Statements before being moved into Item 501 in 1982. See *Integrated Disclosure System Adopting Release*, *supra* note 103; *Rescission of Guides and Redesignation of Industry Guides*, Release No. 33-6384 (Mar. 3, 1982) [47 FR 11476 (Mar. 16, 1982)].

<sup>135</sup> See Proposing Release, *supra* note 5, Section II.D.1.a. at 50997.

<sup>136</sup> See letters from K. Bishop, CCMC, and Fenwick.

<sup>137</sup> See letters from Cravath and Sullivan.

<sup>138</sup> See letter from K. Bishop.

<sup>139</sup> *Id.*

<sup>140</sup> See letter from Sullivan.

<sup>141</sup> 15 U.S.C. 77h.

##### ii. Offering Price of the Securities (Item 501(b)(3))

Item 501(b)(3) requires disclosure on the prospectus front cover page of the price of the securities being offered, the underwriter's discounts and commissions, and the net proceeds that the registrant and any selling security holders will receive.<sup>142</sup> The disclosure must be provided on an aggregate and per share basis, but registrants may present the required information in any format that fits the design of the cover page and is clear, easily read, and not misleading.

In situations where it is not practicable to provide a price for the securities, Instruction 2 to Item 501(b)(1)(3) permits registrants to explain the method by which the price is to be determined.<sup>143</sup> The Commission proposed to amend Instruction 2 to explicitly allow registrants to include a clear statement on the cover page, when applicable, that the offering price will be determined by a particular method or formula that is more fully explained in the prospectus. This proposal was based on the belief that investors may be better served if registrants were given the option to provide a full explanation of the pricing method in the body of the prospectus, with a reference to this more fulsome disclosure displayed prominently on the prospectus cover page.

After considering the responses from a number of commenters who supported this proposal,<sup>144</sup> with no commenters opposed, we are adopting the amendment to Item 501(b)(3). We continue to believe that requiring a detailed explanation of the pricing method on the outside front cover page of the prospectus could reduce the impact of other significant disclosures and is unnecessary so long as the cover page clearly directs investors to the location in the prospectus where the disclosure is provided in full.

##### iii. Market for the Securities (Item 501(b)(4))

Item 501(b)(4) requires a registrant to disclose on the prospectus cover page the name of any national securities

<sup>142</sup> 17 CFR 229.501(b)(3). Item 501(b)(3) also includes specific disclosure requirements for offerings being made on a minimum/maximum basis.

<sup>143</sup> The instruction also provides that if the securities are to be offered at the market price, or if the offering price is to be determined by a formula relating to the market price, the registrant should indicate the market and market price of the securities as of the latest practicable date. The Commission did not propose any change to this portion of the instruction.

<sup>144</sup> See letters from Cravath, Fenwick, Sullivan, and CCMC.

exchanges that list the securities being offered and the trading symbols for those securities. A “national securities exchange” is defined in the Exchange Act as a securities exchange that has registered with the Commission under Section 6 of the Exchange Act.<sup>145</sup> Item 501(b)(4) is specific to “national securities exchanges” and does not, under its terms, require registrants to identify markets that are not national securities exchanges.<sup>146</sup>

The Commission proposed to amend Item 501(b)(4) to require disclosure on the prospectus cover page of the principal United States market or markets for the securities being offered and the corresponding trading symbols based on the premise that the information required by Item 501(b)(4) could be important to investors even as to markets that are not “national securities exchanges.”<sup>147</sup> The Commission proposed to expand the scope of the item only to the principal United States markets where the registrant, through the engagement of a registered broker-dealer, has actively sought and achieved quotation. By limiting the proposal in this way, the Commission acknowledged that registrants cannot always control whether their securities are quoted on an over-the-counter market and should not be burdened with making that determination.

Several commenters supported the proposal,<sup>148</sup> and only one commenter opposed it.<sup>149</sup> The commenter that opposed expanding the cover page disclosure of applicable securities markets stated that the identification of trading markets other than national

securities exchanges on the prospectus cover page may confuse investors by suggesting that the markets were equivalent to national exchanges.<sup>150</sup>

We are adopting amended Item 501(b)(4), as proposed. We continue to believe, as stated in the Proposing Release, that investors would benefit from the addition of this information.<sup>151</sup> In adopting this disclosure requirement, we considered the concern that the presentation of this information on the prospectus cover page might suggest to some investors that the registrant’s principal United States market, while not a national securities exchange, carries the imprimatur of an exchange registered under Section 6(b) of the Exchange Act. It is not clear, however, that providing the name of the principal market on the prospectus cover page, in and of itself, is sufficient to create an inference about the quality of the market, or that such identification carries any implication about the market that would not already be produced by identification of the market under the existing prospectus disclosure requirements of Item 202 and Item 508 of Regulation S–K.<sup>152</sup> Therefore, we do not think that there is a significant risk that investors will equate the principal market or markets listed on the cover page with a national stock exchange.

#### iv. Prospectus “Subject to Completion” Legend (Item 501(b)(10))

Item 501(b)(10) requires a registrant that is using a preliminary prospectus to include a legend advising readers that the information will be amended or completed. The legend also must include a statement that the prospectus is not an offer to sell or a solicitation of an offer to buy securities in any state where the offer or sale is not permitted. The latter statement was introduced in 1958 to harmonize the legend with what was required by state securities administrators at the time.<sup>153</sup>

<sup>150</sup> *Id.* The commenter pointed out that national securities exchanges are registered under Section 6(b) of the Exchange Act and therefore subject to more rigorous requirements than non-registered domestic exchanges. Cover page disclosure of these other exchanges might, in the commenter’s view, give them the “imprimatur” of a national securities exchange, thus complicating the disclosure rather than streamlining it.

<sup>151</sup> See Proposing Release, *supra* note 5, Section II.D.1.c. at 50998.

<sup>152</sup> Item 202 [17 CFR 229.202] requires a description of the registrant’s securities, including relevant market information. Item 508 [17 CFR 229.508] pertains to disclosure about the plan of distribution of the securities offering, including identification of the exchange, if any, on which the securities are to be offered.

<sup>153</sup> See *Amendment of Rules 134 and 433*, Release No. 33–3885 (Jan. 7, 1958) [23 FR 184 (Jan. 10, 1958)]. This requirement was originally in Rule 433, a predecessor to the current requirement.

The legend requirement has remained mostly unchanged since 1958, even after the National Securities Markets Improvement Act (“NSMIA”) allowed for preemption of state blue sky laws in many offerings.<sup>154</sup> The Commission proposed to amend Item 501(b)(10) to permit registrants to exclude from the prospectus the portion of the legend relating to state law for offerings that are not prohibited by state blue sky laws. This change would allow for a more tailored prospectus cover page in recognition of the changes to securities law brought by NSMIA.

The Commission also proposed to streamline Item 501(b) by consolidating existing Item 501(b)(11), regarding the use of Rule 430A, into Item 501(b)(10) for the sake of simplicity without substantive change.

A number of commenters supported the amendments to Item 501(b)(10) that would simplify the “subject to completion” legend on preliminary prospectuses, and no commenters opposed these amendments.<sup>155</sup> Therefore, and for the reasons noted in the Proposing Release, we are adopting the revisions to Item 501(b)(10) as proposed.

#### b. Risk Factors (Item 503(c))

Item 503(c) requires disclosure of the most significant factors that make an offering speculative or risky.<sup>156</sup> This risk factor disclosure was initially called for only in the offering context,<sup>157</sup> but in 2005 the risk factor disclosure requirements were extended to periodic reports and registration statements on Form 10.<sup>158</sup> Consistent with this change, the Commission proposed to relocate Item 503(c) to new Item 105, as Subpart 100 covers a broad category of business information and is not limited to offering-related disclosure.<sup>159</sup>

<sup>154</sup> Public Law 104–290, 110 Stat. 3416 (1996).

<sup>155</sup> See letters from CCMC, Cravath, Fenwick, and Sullivan.

<sup>156</sup> 17 CFR 229.503(c).

<sup>157</sup> See *Guides for Preparation and Filing of Registration Statements*, Release No. 33–4666 (Feb. 7, 1964) [29 FR 2490 (Feb. 15, 1964)] and *Guides for Preparation and Filing of Registration Statements*, Release No. 33–4936 (Dec. 9, 1968) [33 FR 18617 (Dec. 17, 1968)].

<sup>158</sup> See *Securities Offering Reform*, Release No. 33–8591 (July 19, 2005) [70 FR 44722 (Aug. 3, 2005)] (“Securities Offering Reform Adopting Release”).

<sup>159</sup> Additionally, the proposed amendments use the term “registrant” instead of “issuer.” Use of and reference to “registrant” instead of “issuer” was intended to better reflect the application of risk factor disclosure outside of the offering context. The term “registrant” is defined under both the Exchange Act and Securities Act. See Rule 12b–2 [17 CFR 240.12b–2] and Rule 405 [17 CFR 230.405]. The Commission also proposed amendments to several Commission forms that require risk factor disclosure and reference Item 503(c). The proposed

<sup>145</sup> See Section 6 of the Securities Exchange Act of 1934 [15 U.S.C. 78f].

<sup>146</sup> Item 501(b)(4) requires registrants whose securities are listed on “any national securities exchange or the Nasdaq Stock Market” to identify the market(s) and trading symbol(s) for the securities. The Nasdaq Stock Market became operational as a registered national securities exchange on August 1, 2006, following the Commission’s approval of its application for registration on January 13, 2006. A list of registered national exchanges is available on the Commission’s website at <https://www.sec.gov/fast-answers/divisionsmarketregmrxchangesshtml.html>.

<sup>147</sup> The proposed changes to Item 501(b)(4) align with recent amendments to Item 201(a) [17 CFR 229.201(a)]. See *Disclosure Update and Simplification*, Release No. 33–10532 (Aug. 17, 2018) [83 FR 50148 (Oct. 4, 2018)] (the “Disclosure Update and Simplification Release”) at 51688.

<sup>148</sup> See letters from CCMC, Cravath (noting that in connection with the implementation of the European Union Market Abuse Regulation, many registrants have discovered that it is possible for third parties—without any participation by or even notice to the registrant—to list the registrant’s securities on a securities exchange), Fenwick, and Sullivan.

<sup>149</sup> See letter from Nasdaq.

The Commission also proposed amendments that would eliminate the specific risk factor examples that are currently enumerated in Item 503(c). Although Item 503(c) is principles-based, and the Commission has eschewed “boiler plate” risk factors that are not tailored to the unique circumstances of each registrant, the following examples of factors that may make an offering speculative or risky have remained unchanged since the Commission first published guidance on risk factor disclosure in 1964:<sup>160</sup>

- A registrant’s lack of an operating history;
- a registrant’s lack of profitable operations in recent periods;
- a registrant’s financial position;
- a registrant’s business or proposed business; and
- the lack of a market for a registrant’s common equity securities or securities convertible into or exercisable for common equity securities.

As discussed in the Proposing Release, the Commission’s principles-based approach to risk factor disclosure is not consonant with the item’s list of examples of material risks.<sup>161</sup> These examples may not apply to all registrants and may not correspond to the material risks of any particular registrant. In addition, the inclusion of these examples could suggest that a registrant must address each one in its risk factor disclosures, regardless of the significance to its business. Finally, the Commission was concerned that the inclusion of any examples in Item 503(c), whether to illustrate the specific kinds of risks that should be disclosed or generic risks that should be avoided, could anchor or skew the registrant’s risk analysis in the direction of the examples.<sup>162</sup>

Numerous commenters supported the proposed amendments to relocate the risk factor disclosure requirements from Item 503(c) to new Item 105 and eliminate the examples of risk factors that currently appear in the rule.<sup>163</sup> Commenters generally agreed that the

amendments would revise references to Item 503 to specify new Item 105. A number of forms that require risk factor disclosure do not reference Item 503(c). The proposed amendments did not include revisions to these forms. For example, Forms 10-Q and 20-F require risk factor disclosure but do not reference item 503(c).

<sup>160</sup> See *Guides for Preparation and Filing of Registration Statements*, Release No. 33-4666 (Feb. 7, 1964) [29 FR 2490 (Feb. 15, 1964)].

<sup>161</sup> See Proposing Release, *supra* note 5, Section II.D.2. at 50998–10.

<sup>162</sup> See Proposing Release, *supra* note 5, at n. 145.

<sup>163</sup> See letters from American Fuel, BDO, CAQ, Cravath, Edison Electric Institute & American Gas Association, E&Y, Fenwick, Financial Executives, PNC Financial Services Group (“PNC”), Reed Smith, SIFMA, Sullivan, and UnitedHealth.

examples are not helpful because they are written generically and, as such, are not well suited to the particular circumstances and material risks of individual registrants. Some commenters pointed out that the examples may even prompt registrants to include risk factors that address the risks highlighted in the examples even if they are not material to their business.<sup>164</sup> One commenter opposed the elimination of examples in Item 503(c) because, in its view, the examples are helpful guidance that brings focus to the risk factor disclosures.<sup>165</sup> The commenter suggested that eliminating the examples may not further the Commission’s objective of eliciting more specific and relevant risk factor disclosure.

We are adopting the amendments as proposed. With respect to the elimination of the specific examples of material risks currently found in Item 503(c), we continue to think that retaining these examples, which have remained unchanged since they were first articulated in 1964, would be inconsistent with the Commission’s emphasis on principles-based requirements that encourage registrants to provide risk disclosure that is more precisely calibrated to their particular circumstances and therefore more meaningful to investors. By removing this language from the risk factor disclosure rules, we seek to encourage registrants to focus on their own risk identification processes.

#### c. Plan of Distribution (Item 508)

Item 508 requires disclosure about the plan of distribution for securities in an offering, including information about underwriters. Paragraph (a) requires disclosure about the principal underwriters and any underwriters that have a material relationship with the registrant, while paragraph (h) requires disclosure of the discounts and commissions to be allowed or paid to dealers. If a dealer is paid any additional discounts or commissions for acting as a “sub-underwriter,” paragraph (h) allows the registrant to include a general statement to that effect without giving the additional amounts to be sold.

“Sub-underwriter” is not a defined term, and its application may be unclear. “Principal underwriter,” however, is defined in Regulation C as “an underwriter in privity of contract with the issuer of the securities as to which he is an underwriter.”<sup>166</sup> The

Commission accordingly proposed to amend Rule 405 to define the term “sub-underwriter” as a dealer that is participating as an underwriter in an offering by committing to purchase securities from a principal underwriter for the securities but is not itself in privity of contract with the issuer of the securities.<sup>167</sup>

A number of commenters supported the proposed amendments to Rule 405 and no commenters opposed them.<sup>168</sup> We are therefore adopting the amendment to add the definition of “sub-underwriter” to Rule 405, as proposed.

#### d. Undertakings (Item 512)

Item 512 provides undertakings that a registrant must include in Part II of its registration statement, depending on the type of offering. As further described in the Proposing Release, the Commission proposed the following amendments to eliminate undertakings that are duplicative of other rules or that have become unnecessary due to developments since their adoption.<sup>169</sup> Specifically, the Commission proposed to eliminate Item 512(c)<sup>170</sup> in its entirety because it is no longer necessary,<sup>171</sup> and proposed to eliminate the Item 512(d), Item 512(e), and Item 512(f) undertakings, because they are obsolete.<sup>172</sup>

<sup>167</sup> The only other use of the term “sub-underwriter” or “subunderwriter” in Regulation S-K, the Securities Act rules, or the Exchange Act rules is in Rule 491. The Commission proposed to amend Rule 491 to reference “sub-underwriter,” consistent with the proposed amendments to Rule 405. The proposed definition of sub-underwriter would not change the meaning of that term in Rule 491.

<sup>168</sup> See letters from CCMC, Cravath, and Sullivan.  
<sup>169</sup> See Proposing Release, *supra* note 5, Section II.D.4. at 51000–1.

<sup>170</sup> 17 CFR 229.512(c).

<sup>171</sup> See Proposing Release, *supra* note 5, Section II.D.4. at 51000. Item 512(c) sets forth undertakings that a registrant must include if it registers a warrant or rights offering to existing security holders and the securities not purchased by those security holders will be reoffered to the public. The Item requires a registrant to supplement the prospectus to disclose the results of the subscription offer and the terms of any subsequent reoffer to the public. If any public reoffer is made on different terms than the offer to existing security holders, the registrant must undertake to file a post-effective amendment. The purpose of the undertaking is to provide current information about warrants or rights offerings. See FAST ACT Report, *supra* note 7, at Recommendation E.8. Given that the registrant would already have to register and disclose the offering to existing security holders, as well as the reoffering to the public, the undertaking is duplicative and unnecessary. Furthermore, disclosure of material changes in the terms of the offering would also be required as part of the Item 512(a)(1) undertaking, thus obviating the need for Item 512(c).

<sup>172</sup> *Id.* at 51000–1. Item 512(d) is applicable when the securities to be registered are to be offered at

A number of commenters supported the proposed amendments to the undertakings and no commenters opposed them.<sup>173</sup> Accordingly, and for the reasons noted in the Proposing Release, we are amending Item 512 to remove the undertakings in paragraphs 512(c), (d), (e), and (f), as proposed.

## 5. Exhibits

### a. Description of Registrant's Securities (Item 601(b)(4))

Item 202 requires registrants to provide a brief description of their registered capital stock, debt securities, warrants, rights, American Depositary Receipts, and other securities.<sup>174</sup> Registrants provide Item 202 disclosure about registered securities in their registration statements,<sup>175</sup> but are not required to provide this disclosure in their Form 10-K or Form 10-Q.<sup>176</sup>

The Commission proposed to amend Item 601(b)(4)<sup>177</sup> to require registrants to provide the information required by Item 202(a)-(d) and (f) as an exhibit to Form 10-K, rather than limiting this

competitive bidding. Item 512(e) sets forth undertakings that are required if the registration statement incorporates by reference in the prospectus all or any part of the annual report to security holders meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Exchange Act. Item 512(f) pertains to equity offerings of registrants that are not subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act. Each of these items is no longer necessary because of prior changes in our rules, as described in the Proposing Release. For example, the undertaking in Item 512(d) arose from a requirement in the Public Utility Holding Company Act of 1935 ("PUHCA") that public utility company securities be sold through competitive bidding. That requirement was rescinded in 1994 and PUHCA was repealed by Congress in 2005.

<sup>173</sup> See letters from Cravath, FedEx, Nasdaq, Sullivan, and CCMC.

<sup>174</sup> Items 202(a)-(d) and (f) [17 CFR 229.202(a)-(d) and (f)]. Item 202(e), "Market information for securities other than common equity," is outside the scope of this rulemaking; it requires that if securities other than common stock are to be registered and there is an established trading market for such securities, registrants are required to provide market information for such securities comparable to that required by Item 201(a) of Regulation S-K.

<sup>175</sup> Item 202 disclosure is often incorporated by reference into a registration statement on Form 8-A from a prior registration statement on Form S-1. See Concept Release, *supra* note 9, at Section IV.D.2.

<sup>176</sup> Registrants are required to file complete copies of their articles and bylaws as exhibits to Form 10-K, but they are not required to provide the descriptions called for by Item 202. See Item 601(b)(3) [17 CFR 229.601(b)(3)]. Also, under Accounting Standards Codification ("ASC") Topic 505-10-50-3, registrants are required to summarize the "pertinent rights and privileges of the various securities outstanding" in the notes to their financial statements. ASC Topic 470-10-50-5 requires the same information for debt securities. While the date of sale is not required, registrants usually include it in their discussions of the rights and privileges of securities sold.

<sup>177</sup> 17 CFR 229.601(b)(4).

disclosure to registration statements.<sup>178</sup> The proposed amendments were intended to be in addition to the current requirement to file a complete copy of the amended articles of incorporation or bylaws under Item 601(b)(3)<sup>179</sup> in order to increase investors' ease of access to information about the rights and obligations of each class of securities registered.<sup>180</sup>

We received responses from a number of commenters on the proposal to require Item 202 information as an exhibit to Form 10-K.<sup>181</sup> Several commenters supported the Commission's proposal to consolidate into one exhibit the description of a registrant's securities, but emphasized that the ability of registrants to incorporate the required information by reference to prior filings was essential to minimizing the registrants' compliance burden.<sup>182</sup> One commenter acknowledged the initial, one-time burden required to comply with the new exhibit requirement, but thought this cost was outweighed by the benefit to investors from making the information easier to locate.<sup>183</sup> This commenter stated that the effect of the requirement would be to "put all registrants on a level playing field."<sup>184</sup> In contrast, some commenters opposed the proposal because, in their view, the information required by new Item 601(b)(4)(vi) would be duplicative of information

<sup>178</sup> To the extent that a registrant has previously filed an exhibit to a Form 10-K containing Item 202 disclosure, under the proposal it could incorporate that exhibit by reference and hyperlink to the previously filed exhibit in future Form 10-K filings, assuming that the information contained therein remains unchanged. See Instruction 3 to proposed Item 601(b)(4)(vi).

<sup>179</sup> See Item 601(b)(3) of Regulation S-K [17 CFR 229.601(b)(3)]. The Commission proposed to amend Item 601(b)(4) instead of Item 601(b)(3) because (b)(4) is consistent with Item 202's requirement to provide a description of capital stock that is registered, while (b)(3) is specific to the articles of incorporation and bylaws.

<sup>180</sup> Proposed Item 601(b)(4)(vi) would require Item 202 disclosure only for securities that are registered under Section 12 of the Exchange Act. Because Item 202(e) requires Item 201(a) market information for securities other than common equity where there is an established trading market for those securities, proposed Item 601(b)(4)(vi) did not include Item 202(e).

<sup>181</sup> See letters from Ball Corporation ("Ball"), CCMC, CII, Cravath, Davis Polk, Fenwick, Financial Executives, Reed Smith, SIFMA, Soc. For Corp Gov., and Sullivan.

<sup>182</sup> See, e.g., letters from Davis Polk, Fenwick, Society for Corp. Gov., and Sullivan. One commenter indicated that without the option to incorporate by reference, preparation of new exhibits with multiple classes of registered debt securities would exceed the associated 0.5 hour paperwork burden estimated in the Proposing Release because of the time needed to prepare the disclosure and have it reviewed by outside counsel. See letter from Davis Polk.

<sup>183</sup> See letter from SIFMA.

<sup>184</sup> *Id.*

already readily available to investors on EDGAR.<sup>185</sup>

We are adopting amendments to Item 601(b)(4) as proposed. Although the information required by this item will necessarily overlap with disclosure that may already be found in a registrant's publicly available registration statements, we think that providing all of this information in one location is a better alternative for investors than requiring them to search for and piece together the information they need from multiple documents that may span many years. By virtue of new 601(b)(4)(vi), investors will be able to easily locate an updated description of their rights as security holders by referring to the registrant's most recent annual report. We believe this will facilitate investors' access to information without imposing significant additional costs on registrants, particularly given the registrant's ability to incorporate the information by reference<sup>186</sup> and the existing requirement to hyperlink exhibits that are incorporated by reference.<sup>187</sup>

We note that these amendments do not change existing disclosure obligations under Form 8-K and Schedule 14A, which require registrants to disclose certain modifications to the rights of their security holders and amendments to their articles of incorporation or bylaws.<sup>188</sup> Under new Item 601(b)(4)(vi), any modifications and amendments during a fiscal year should also be reflected in the Item 202 disclosure provided in an exhibit to the

<sup>185</sup> See letters from Ball, Cravath, and Financial Executives (noting obligations under Form 8-K and Schedule 14A). See also Proposing Release, *supra* note 5 at Section II.E.1. at nn. 180 and 181.

<sup>186</sup> See Instruction 3 to new Item 601(b)(4)(vi).

<sup>187</sup> See Item 601(a)(2) of Regulation S-K.

<sup>188</sup> Item 3.03 of Form 8-K requires disclosure of material modifications to rights of security holders while Item 5.03 requires disclosure of amendments to the articles of incorporation or bylaws for amendments not disclosed in a proxy or information statement. Item 5.03 of Form 8-K also requires disclosure of changes in fiscal year other than by means of a submission to a vote of security holders through the solicitation of proxies (or otherwise) or an amendment to the articles of incorporation or bylaws.

Item 12 of Schedule 14A requires disclosure if action is to be taken regarding the modification of any class of securities of the registrant, or the issuance or authorization for issuance of securities of the registrant in exchange for outstanding securities. Section (b) of Item 12 requires disclosure of any material differences between the outstanding securities and the modified or new securities in respect to any of the matters concerning which information would be required in the description of the securities in Item 202 of Regulation S-K. Item 19 of Schedule 14A requires disclosure of amendments to the registrant's charter, bylaws, or other documents.

registrant's annual report for such year.<sup>189</sup>

b. Additional Information Omitted From Exhibits (Item 601 and Investment Company Forms)<sup>190</sup>

i. Schedules and Attachments to Exhibits

Under existing rules in Item 601 of Regulation S–K, registrants generally must file complete copies of any required exhibits. Very often, these exhibits include a number of schedules, appendices, and other similar attachments which can be quite lengthy but not necessarily material to investors. Except for paragraph (b)(2) of Item 601,<sup>191</sup> which applies only to material plans of acquisition, reorganization, arrangement, liquidation, or succession, registrants must file every required exhibit under Item 601 in its entirety, irrespective of the materiality of particular information in the exhibits. Because the information in certain schedules or similar attachments to the exhibits may not be material to investors, a uniform filing requirement for this information is not commensurate with the corresponding costs and burden imposed on registrants, particularly when the schedules, appendices, and other attachments contain proprietary or otherwise sensitive information.

Consequently, the Commission proposed Item 601(a)(5) to expand the existing accommodation in Item 601(b)(2) to include all exhibits filed under Item 601. Similar to current Item 601(b)(2), proposed Item 601(a)(5) would permit registrants to omit entire schedules and similar attachments to required exhibits, provided: (i) They did not contain material information and (ii) were not otherwise disclosed in the exhibit or the disclosure document. Just as with Item 601(b)(2), proposed Item 601(a)(5) was qualified by the requirement that the filed exhibit must contain a list briefly identifying the contents of any omitted schedules and

attachments.<sup>192</sup> The Commission also requested comment on whether it should apply the proposed amendments to forms that contain their exhibit requirements in the form and do not separately reference Item 601 of Regulation S–K. The Commission similarly requested comment on whether it should amend the investment company rules or forms to permit investment companies to omit entire schedules and attachments to required exhibits on similar terms.

Commenters generally supported the proposal, with several noting the excessive burden on registrants under the current rules without a corresponding benefit to investors.<sup>193</sup> One commenter stated that the rationale for the proposed amendments to Item 601 of Regulation S–K was applicable to other forms,<sup>194</sup> while another favored expanding the scope of the proposal specifically to include rules and forms under the Investment Company Act.<sup>195</sup> Another commenter stated that the required list identifying any omitted schedules or attachments was unnecessary if a comparable list already exists in the exhibit.<sup>196</sup>

We are adopting new Item 601(a)(5) as proposed. When the Commission first adopted Item 601(b)(2) in 1980, it noted that many of the schedules then received by the staff were “not material for investor information or protection and are unnecessary for Commission review purposes.”<sup>197</sup> The same reasoning provides the basis for expanding the accommodation in Item 601(b)(2) to other exhibits filed pursuant to Item 601. For similar reasons, we are adding comparable provisions to the

<sup>192</sup> See proposed Item 601(a)(5) of Regulation S–K. Unlike the current version of Item 601(b)(2), proposed Item 601(a)(5) would not require registrants to include with their list of omitted schedules an explicit agreement to furnish a supplemental copy of any omitted schedule to the Commission upon request. Nonetheless, registrants may be required to provide a copy of any omitted schedule to the Commission staff upon request. Securities Act Rule 418 [17 CFR 230.418] states that the Commission or its staff may, where it is deemed appropriate, request supplemental information concerning the registrant or a registration statement, among other things. Exchange Act Rule 12b–4 [17 CFR 240.12b–4] similarly indicates that the Commission or its staff may, where it is deemed appropriate, request supplemental information concerning the registrant, a registration statement, and a periodic or other report filed under the Exchange Act.

<sup>193</sup> See letters from Business Roundtable, CCMC, Cravath, Davis Polk, FedEx, Fenwick, Financial Executives, Grumman, PNC, SIFMA, Society for Corp. Gov., Sullivan, and UnitedHealth.

<sup>194</sup> See letter from Society for Corp. Gov.

<sup>195</sup> See letter from ICI.

<sup>196</sup> See letter from Cravath.

<sup>197</sup> *Amendments Regarding Exhibit Requirements*, Release No. 33–6230 (Aug. 27, 1980) [45 FR 58822 (Sept. 5, 1980)], at 5.

exhibit requirements of Item 1016 of Regulation M–A,<sup>198</sup> our investment company registration forms, and Form N–CSR.<sup>199</sup> As discussed, each exhibit that includes omitted schedules or other attachments in reliance on these new provisions must contain a list briefly identifying the contents of each such schedule or attachment, which is a requirement that mirrors the language in Item 601(b)(2). However, in response to one commenter's suggestion, we are clarifying that the amendments do not require that registrants prepare a separate list if that information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments.

ii. Personally Identifiable Information<sup>200</sup>

The Commission generally does not publish or make available information that “would constitute a clearly unwarranted invasion of personal privacy.”<sup>201</sup> Exhibits filed pursuant to Item 601 may include sensitive personally identifiable information, such as bank account numbers, social security numbers, home addresses, and similar information (“PII”).

As a matter of practice, the staff generally does not object where a registrant omits PII from exhibits without also submitting a confidential treatment request under Rule 406 or Rule 24b-2. To codify this current staff practice, the Commission proposed new Item 601(a)(6) to allow registrants to omit PII from their required Item 601 exhibits without submitting a confidential treatment request for the information. In proposing this amendment, the Commission also anticipated the added benefit of better safeguarding PII by limiting its dissemination. In the Proposing Release, the Commission asked whether similar amendments should be made to forms that contain their exhibit requirements in the form and do not separately

<sup>198</sup> See new Instruction 1 to Item 1016.

<sup>199</sup> See new Instruction 2 to Item 28 of Form N–1A; new Instruction 4 to Item 25.2 of Form N–2; new Instruction 3 to Item 29(b) of Form N–3; new Instruction 3 to Item 24(b) of Form N–4; new Instruction 1 of Instructions as to Exhibits of Form N–5; new Instruction 1 to Item 26 of Form N–6; new Instruction 1 to Item 16 of Form N–14; new Additional Instruction 1 to the Instructions as to Exhibits of Form S–6; new Instruction 1 to IX. Exhibits of Form N–8B–2; and new Instruction 2 to Item 13 of Form N–CSR.

<sup>200</sup> See *supra* at Section II.A.2. for a discussion of our amendments to the exhibit requirements in Item 601(b)(10) pertaining to material contracts.

<sup>201</sup> 17 CFR 200.80(b)(6) (exempting personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy).

<sup>189</sup> Over the course of a given fiscal year, it is possible that a registrant may make various non-material changes to the rights and privileges of its securities that do not require separate disclosure on Form 8–K. However, if any changes are made, whether material or non-material, new Item 601(b)(4)(vi) requires a registrant to update the description of securities in the exhibit filed with its Form 10–K.

<sup>190</sup> See *supra* at Section II.A.2. for a discussion of our amendment to the exhibit requirements in Item 601(b)(10) pertaining to material contracts.

<sup>191</sup> Item 601(b)(2) states that registrants shall not file schedules or similar attachments to material plans of acquisition, reorganization, arrangement, liquidation, or succession unless they contain information material to an investment decision and unless that information is not otherwise disclosed in the agreement or the disclosure document.

reference Item 601 of Regulation S–K, as well as investment company forms.

Several commenters supported the proposed amendment to Item 601, and no commenters opposed.<sup>202</sup> In addition, one commenter indicated that the same rationale applied to other forms<sup>203</sup> and two other commenters specifically recommended that a similar accommodation be extended to investment companies.<sup>204</sup>

We are adopting new Item 601(a)(6) as proposed. For the same policy reasons as discussed above, we are also adding comparable provisions to the exhibit requirements of Item 1016 of Regulation M–A,<sup>205</sup> our investment company registration forms, and Form N–CSR.<sup>206</sup> Under the amendments, registrants may redact information if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy. Registrants who choose to avail themselves of this accommodation may provide their exhibit with appropriate redactions and need not include an analysis supporting the redactions at the time of filing.

#### c. Material Contracts (Item 601(b)(10)(i))

Item 601(b)(10)(i) requires registrants to file every material contract not made in the ordinary course of business, provided that one of two tests is met: (i) The contract must be performed in whole or in part at or after the filing of the registration statement or report, or (ii) the contract was entered into not more than two years before that filing.<sup>207</sup> The first test captures contracts that have not been fully performed prior to the filing date. The second test—the two-year look back—captures material contracts that were fully performed before the filing date.<sup>208</sup>

<sup>202</sup> See, e.g., letters from American Fuel, CCMC, Cravath, Davis Polk, FedEx, Grumman, ICI, PNC, and Society for Corp. Gov.

<sup>203</sup> See *supra* note 194.

<sup>204</sup> See letters from ICI and Society for Corp. Gov.

<sup>205</sup> See new Instruction 2 to Item 1016.

<sup>206</sup> See new Instruction 3 to Item 28 of Form N–1A; new Instruction 5 to Item 25.2 of Form N–2; new Instruction 4 to Item 29(b) of Form N–3; new Instruction 4 to Item 24(b) of Form N–4; new Instruction 2 of Instructions as to Exhibits of Form N–5; new Instruction 2 to Item 26 of Form N–6; new Instruction 2 to Item 16 of Form N–14, new Additional Instruction 2 to the Instructions as to Exhibits of Form S–6; new Instruction 2 to IX. Exhibits of Form N–8B–2; and new Instruction 3 to Item 13 of Form N–CSR.

<sup>207</sup> Item 601(b)(10)(i) of Regulation S–K [17 CFR 229.601(b)(10)(i)].

<sup>208</sup> The two-year look back is included in Schedule A of the Securities Act [15 U.S.C. 77aa(24)] and serves as a “cutoff period” so registrants would not have to file material contracts that may have been fully performed many years prior to registration. When Section 12(g) was added to the Exchange Act in 1964, the Commission was authorized to issue rules requiring such material

The Commission proposed amendments to Item 601(b)(10)(i) that would limit the two-year look back test to “newly reporting registrants,” as that term was defined in the proposed revision to Instruction 1 of Item 601(b)(10). The proposal required registrants meeting this definition to file material agreements for the two-year look back period. The proposed amendments were intended to help ensure that investors receive access to agreements containing material information, including agreements entered into by newly reporting registrants up to two years prior to the commencement of their reporting obligations. Registrants with established reporting histories, however, would no longer be subject to the two-year look back requirement because investors would continue to have access to any material agreements previously filed on EDGAR. As such, the amendments were proposed to streamline reporting obligations while maintaining investor protections.

A number of commenters supported the proposed amendments, and no commenters opposed them.<sup>209</sup> Accordingly, we are adopting amendments to Item 601(b)(10)(i) and Instruction 1 of Item 601(b)(10) as proposed. We believe restricting the two-year look back to newly-reporting registrants is consistent with the original objective of the disclosure requirement and will help to eliminate unnecessary disclosures without impairing investor information or protection. Accordingly, under the revised item all registrants are required to file as an exhibit every contract not made in the ordinary course of business that is material to the registrant and is to be performed in whole or in part at or after the filing of the registration statement or report. In addition, newly reporting registrants are also required to file every contract that was not made in the ordinary course of business that is material to the registrant and that was entered into not more than two years before.<sup>210</sup>

As proposed, we are adopting a definition of “newly reporting registrant” that includes:

#### • Registrants that are not subject to the reporting requirements of Section

contracts to be filed with Exchange Act reports. See Section 12(b)(1)(I) of the Exchange Act; H.R. Rep. No. 88–1418, 83rd Cong., 2nd Sess., 1964. Prior to the enactment of Section 12(g), the Exchange Act reporting requirements were applicable only to listed companies.

<sup>209</sup> See letters from CCMC, Cravath, Fenwick, SIFMA, and Sullivan.

<sup>210</sup> Item 601(b)(10)(i), as revised.

13(a) or 15(d) of the Exchange Act at the time of filing;

- registrants that have not filed an annual report since the revival of a previously suspended reporting obligation;<sup>211</sup> and
- any registrant that (a) was a shell company, other than a business combination related shell company, as defined in Rule 12b–2 under the Exchange Act (17 CFR 240.12b–2), immediately before completing a transaction that has the effect of causing it to cease being a shell company and (b) has not filed a registration statement or Form 8–K as required by Items 2.01 and 5.06 of that form, since the completion of such transaction (or, in the case of foreign private issuers, has not filed a Form 20–F since the completion of the transaction).<sup>212</sup>

#### d. Application to Foreign Private Issuers

The Commission previously adopted amendments to conform the exhibit requirements in Form 20–F to the requirements in Item 601.<sup>213</sup> To maintain a consistent approach to the exhibit requirements for domestic registrants and foreign private issuers, the Commission proposed amendments to require foreign private issuers to provide information in exhibit filings comparable to the information provided by domestic registrants under the proposed amendments to Item 601. Specifically, the Commission proposed to amend the “Instructions to Exhibits” in Form 20–F to include revised language comparable to Items 601(a)(5), Item 601(a)(6), Item 601(b)(4)(vi), Item 601(b)(10)(i), Item 601(b)(10)(iv), and Item 601(b)(21) of Regulation S–K.

In the Proposing Release, the Commission asked whether it should amend the exhibit requirements of Form 20–F so that they are consistent with the requirements under Item 601. A few

<sup>211</sup> In the case of a registrant with a suspended reporting obligation that, less than two years later, is revived, the requirement to file material agreements for the two-year look back period may be satisfied by incorporating by reference and hyperlinking to agreements previously filed on EDGAR and filing any material agreements entered into while the registrant was not reporting. See Exhibit Hyperlinks Adopting Release, *supra* note 10, at 14135.

<sup>212</sup> The definition of “newly reporting registrant” does not include reporting companies completing merger transactions with business combination-related shell companies.

<sup>213</sup> See *International Disclosure Standards Release*, Release No. 33–7637 (Feb. 2, 1999) [64 FR 6261 (Feb. 9, 1999)] (expressing the Commission’s intention “to conform the exhibit requirements for Form 20–F with the exhibit requirements for registration statements filed by U.S. issuers under the Exchange Act” and stating that all of the Form 20–F exhibit requirements “are required for domestic issuers filing a registration statement on Form 10 or an annual report on Form 10–K”).

commenters supported the proposal,<sup>214</sup> and no commenters opposed.

Accordingly, and for the reasons noted in the Proposing Release, we are adopting amendments to Form 20-F to align the exhibit requirements of the form with similar amendments we are adopting today that are applicable to domestic registrants. In each case, we believe that the justifications for the proposed amendments to Item 601 are equally applicable to Form 20-F.<sup>215</sup>

#### 6. Incorporation by Reference<sup>216</sup>

To reduce duplicative disclosure, registrants have been permitted to incorporate previously filed information into their filings since the enactment of the Securities Act and the Exchange Act.<sup>217</sup> Initially, incorporation by reference was limited to exhibits, but over time the Commission has increasingly permitted incorporation by reference in other contexts. The rules and instructions governing incorporation by reference are now found in a variety of regulations, including Regulation S-K, Regulation C, Regulation 12B, and many of the Commission's forms.

Consistent with our mandate under the FAST Act, the Commission proposed amendments to revise Item 10(d), Rule 411, Rule 12b-23, and a number of our forms to simplify and modernize these rules while still providing all material information. The Commission also proposed to rescind Rule 12b-32. In addition, to provide for a consistent set of incorporation by reference rules for investment companies and investment advisers, the Commission proposed parallel amendments to Rule 0-4 and a number of forms under the Investment Company Act, certain conforming amendments to Rule 0-6 under the Investment Advisers Act, and the rescission of Rules 8b-23, 8b-24, and 8b-32 under the Investment Company Act (certain provisions of which would be consolidated into the amendments to Rule 0-4).

<sup>214</sup> See letters from Cravath and Sullivan.

<sup>215</sup> The Commission did not propose similar changes to the exhibit requirements of Form 40-F. Form 40-F generally permits Canadian issuers to use Canadian disclosure documents to satisfy the Commission's registration and disclosure requirements. As a result, the exhibit requirements in Form 40-F are largely in accordance with Canadian disclosure standards.

<sup>216</sup> For a discussion of our amendments that impact the ability to incorporate by reference or cross-reference information into the financial statements, see Section II.A.3 *supra*.

<sup>217</sup> See Federal Trade Commission Release No. 33-47 (Sept. 22, 1933) (allowing for incorporation by reference of exhibits filed with registration statements); Release No. 34-51 (Nov. 27, 1934) (allowing for incorporation by reference of exhibits filed with the Commission under the Exchange Act or filed with an exchange).

The proposed amendments were intended to streamline the requirements associated with incorporation by reference and facilitate investor access to incorporated documents through the use of hyperlinks. The proposed amendments were also consistent with the Commission's longstanding acceptance of incorporation by reference in the interests of encouraging registrants to eliminate duplicative disclosures.

#### a. Item 10(d)

Item 10 of Regulation S-K contains general requirements on the application of Regulation S-K and Item 10(d) focuses on incorporation by reference.<sup>218</sup> Item 10(d) states that where rules, regulations, or instructions to the forms permit incorporation by reference, a document may be incorporated by reference to the specific document and to the prior filing or submission in which that document was physically filed or submitted. Item 10(d) generally prevents registrants from incorporating by reference a portion of a document that itself also incorporates pertinent information by reference.<sup>219</sup> It also prohibits incorporating documents by reference if they have been on file with the Commission for more than five years and do not fall within one of the exceptions provided in the rule.<sup>220</sup>

As discussed in the Proposing Release, the Commission proposed to eliminate the five-year limit in Item 10(d).<sup>221</sup> Given the broad exceptions to the rule and the current practice of retaining documents electronically, we believe the five-year limit now serves little purpose and may lead to confusion about which documents may be incorporated by reference.<sup>222</sup> Under the proposed amendments, a registrant

<sup>218</sup> 17 CFR 229.10(d).

<sup>219</sup> Indirect incorporation by reference is permitted when the registrant is expressly required to incorporate a document by reference and, in the case of asset-backed issuers, under Item 1100(c) of Regulation AB [17 CFR 229.1100(c)]. See Item 10(d).

<sup>220</sup> See Proposing Release, *supra* note 5, Section II.F.1.a. at 51007-8.

<sup>221</sup> *Id.* Without the provisions relating to the five-year limit, little substance remains in Item 10(d). Therefore, to simplify the requirements, the Commission proposed to move the remaining provision in Item 10(d) prohibiting indirect incorporation by reference into the other rules governing incorporation by reference.

<sup>222</sup> We believe that it is very unlikely that a registrant would attempt to incorporate by reference to a document that was filed with the Commission but is no longer available because it was not submitted on EDGAR and has been destroyed pursuant to the Records Control Schedule. For example, the Commission retains Securities Act and Exchange Act registration statements, reports, and proxy materials that have not been filed on EDGAR for 30 years. See Records Control Schedule [17 CFR 200.80f].

would not be permitted to incorporate by reference to a destroyed document because it would render its disclosure incomplete, unclear, or confusing.<sup>223</sup>

Several commenters supported the proposal, and no commenters opposed.<sup>224</sup> Therefore, and for the reasons noted in the Proposing Release, we are adopting these amendments as proposed.

#### b. Securities Act Rule 411, Exchange Act Rule 12b-23 and Rule 12b-32, and Related Rules Under the Investment Company Act and Investment Advisers Act

Rule 12b-23 governs incorporation by reference for registration statements filed pursuant to Sections 12(b) and 12(g) of the Exchange Act and reports filed pursuant to Sections 13 and 15(d) of the Exchange Act.<sup>225</sup> Rule 12b-23 broadly allows for incorporation by reference in answer, or partial answer, to any item of an Exchange Act registration statement or report. Rule 12b-32 governs incorporation by reference for exhibits filed with registration statements and reports. Rule 411 governs incorporation by reference for registration statements filed under the Securities Act, including exhibits thereto.<sup>226</sup> Rule 411 restricts incorporation by reference in a prospectus unless otherwise provided in the appropriate form but allows for incorporation by reference similar to Rule 12b-23 for the non-prospectus portions of a registration statement.<sup>227</sup>

Rule 0-4 provides general incorporation by reference rules for investment company registration statements, applications, and reports filed with the Commission. Rule 8b-23 (additional incorporation by reference rules for registration statements and reports), Rule 8b-24 (rules regarding summaries or outlines of documents), and Rule 8b-32 (incorporation of exhibits by reference) provide

<sup>223</sup> See, e.g., proposed Rule 411(e) and Rule 12b-23(e).

<sup>224</sup> See letters from Chamber, Cravath, Fenwick, Financial Executives, Nasdaq, Society for Corp. Gov., Sullivan, UnitedHealth, and ICI.

<sup>225</sup> See Rule 12b-1 [17 CFR 240.12b-1] (setting forth the scope of Regulation 12B).

<sup>226</sup> See Rule 400 [17 CFR 230.400] (setting forth the scope of Regulation C).

<sup>227</sup> See Integrated Disclosure System Adopting Release, *supra* note 103; *Proposed Revision of Regulation C, Registration and Regulation 12B, Registration and Reporting*, Release No. 33-6333 (Aug. 6, 1981) [46 FR 41971 (Aug. 18, 1981)] ("While it is generally proper to prevent prospectuses from incorporating exhibits which are not delivered, the Commission does not believe it is necessary to impose such limits in connection with Exchange Act reports which are not actually delivered in registered public offerings of securities.").

additional incorporation by reference rules for investment company registration statements and reports. Rule 0–6 governs incorporation by reference for investment adviser applications for Commission orders under the Investment Advisers Act other than applications for registration as an investment adviser.

#### i. Exhibit and Other Filing Requirements

Rule 12b–23(a)(3) under the Exchange Act requires that copies of any information incorporated by reference must be filed as an exhibit, with limited exceptions.<sup>228</sup> Rule 411(b)(4) under the Securities Act, which is more limited and pertains to non-prospectus information that is incorporated by reference, requires that the incorporated information be filed as an exhibit if it does not comply with the five-year limit in Item 10(d). Rule 8b–23 generally requires investment company registrants to file with a registration statement or report a copy of any registration statement, report, or prospectus from which information is incorporated by reference, except in cases where the registration statement, report, or prospectus is filed electronically.<sup>229</sup>

<sup>228</sup> See Rule 12b–23(a)(3) [17 CFR 240.12b–23(a)(3)] (providing exceptions for a proxy or information statement incorporated by reference in response to Part III of Form 10–K, a form of prospectus filed pursuant to Rule 424(b) [17 CFR 230.424(b)] incorporated by reference in response to Item 1 of Form 8–A, and information filed on Form 8–K). This provision was introduced in 1971 so that then-existing microfiche technology for the public dissemination of reports and documents filed with the Commission could function properly. See *Registration and Reporting and Form for Annual Reports of Employee Stock Purchase Plans*, Release No. 34–9048 (Jan. 4, 1971) [36 FR 4483 (Mar. 6, 1971)] (“In order that the microfiche system for the public dissemination of reports and documents filed with [the] Commission may work, the amended rule requires that copies of information or financial statements incorporated by reference, or copies of the pertinent pages of any document containing such information or statement, be filed with the registration statement or report in which it is so incorporated.”).

<sup>229</sup> See Rule 8b–23(a) [17 CFR 270.8b–23(a)]. In addition, Rule 0–4 and Rule 0–6 permit the incorporation by reference as an exhibit in any registration statement, application or report (in the case of Rule 0–4) or in any application (in the case of Rule 0–6) any document or part thereof previously or concurrently filed with the Commission. Both rules also permit the incorporation by reference of financial statements (or parts thereof), although Rule 0–6 specifies that the financial statements (or parts thereof) that are incorporated are to be filed as exhibits. For consistent rules under both Acts, the Commission proposed amendments to Rule 0–4 to specify that financial statements may be filed as exhibits to investment company applications, as Rule 0–6 currently specifies with respect to applications filed under the Investment Advisers Act.

Furthermore, if the number of copies of any document from which information is incorporated by reference is less than the number of copies

The Commission proposed to eliminate these requirements to make the rules for incorporation by reference more consistent, and to apply consistent requirements for incorporation by reference under the Investment Company Act and Investment Advisers Act. We no longer believe that these requirements are necessary, as most Exchange Act filings are made publicly available on EDGAR, and as we generally do not have similar exhibit filing requirements for Securities Act registration statements.<sup>230</sup>

The Commission also proposed to eliminate the corresponding exhibit requirement in Item 601(b)(99)(ii) of Regulation S–K, which was adopted in connection with Rule 12b–23(a) and Rule 411(b)(4).<sup>231</sup> In addition to Item 601(b)(99), other provisions in Item 601 require documents to be filed as exhibits only when they are incorporated by reference into a filing. For example, Item 601(b)(13) requires a registrant to file an annual report to security holders, Form 10–Q, or quarterly report to security holders as an exhibit when the registrant incorporates all or a portion of such a report by reference. Although annual reports to security holders are readily available to investors and the staff outside of EDGAR, we believe it is appropriate to retain the exhibit requirement in these circumstances because some registrants satisfy their disclosure requirements by incorporating a significant amount of disclosure from these reports. The Commission did not propose to eliminate these other exhibit filing

required to be filed with a registration statement, application, or report, Rule 0–4 and Rule 0–6 require an investment company or applicant, respectively, to file as many additional copies of the document incorporated by reference as may be necessary to meet the requirements of the registration statement, application, or report. See Rule 0–4(a), Rule 0–6(a). The Commission proposed to eliminate the requirement to file additional copies from Rule 0–4 because most investment company filings are available on EDGAR. Although investment adviser applications are filed in paper format, in the staff’s experience, those applications rarely incorporate by reference information as permitted by Rule 0–6. For our regulatory purposes, we do not believe that the number of copies specified in current Rule 0–6 is needed. Thus, for the foregoing reasons and for consistency purposes, the Commission similarly proposed to eliminate the requirement to file additional copies from Rule 0–6.

<sup>230</sup> Investment advisers register and submit some filings to the Commission electronically through the Investment Adviser Registration Depository (“IARD”).

<sup>231</sup> See *Integrated Disclosure System Adopting Release*, *supra* note 103 (adopting Item 601(b)(28)(ii), which is now found in Item 601(b)(99)(ii)) and *Proposed Revision of Regulation S–K and Proposed Rescission of Guides for the Preparation and Filing of Registration Statements and Reports*, Release No. 33–6332 (Aug. 6, 1981) [46 FR 41925 (Aug. 18, 1981)].

requirements in Item 601. Nonetheless, the Commission did propose to eliminate the requirement in Item 601(b)(13) to file a Form 10–Q as an exhibit when it is specifically incorporated by reference into a prospectus. This provision will no longer be necessary because, under the rules we are adopting, a registrant will be required to include a hyperlink to any information that is incorporated by reference to a document available on EDGAR.<sup>232</sup>

Several commenters supported the proposal and no commenters opposed it.<sup>233</sup> Therefore, and for the reasons noted in the Proposing Release, we are adopting the amendments, as proposed.

#### ii. Hyperlinks

The Commission proposed to facilitate greater investor access to disclosure by amending Rule 411, Rule 12b–23, and Rule 0–4 to require hyperlinks to information that is incorporated by reference if that information is available on EDGAR.<sup>234</sup> The Commission recently adopted rules requiring hyperlinks to most exhibits filed pursuant to Item 601, Form F–10,<sup>235</sup> or Form 20–F.<sup>236</sup> To accommodate hyperlinks, those filings must be made in HTML format.<sup>237</sup> Accordingly, the Commission proposed to expand the requirement to file documents in HTML to include filings that are subject to the hyperlinking requirements proposed in Rule 411, Rule 12b–23, and Rule 0–4.

Commenters generally supported the proposals,<sup>238</sup> although some thought it would be helpful for the Commission to provide further clarification on some aspects of the rule.<sup>239</sup> One commenter suggested that the Commission make

<sup>232</sup> See *infra* Section II.B.6.b.ii.

<sup>233</sup> See letters from American Fuel, CAQ, Chamber, Cravath, Davis Polk, E&Y, Fenwick, Piercy Bowler, PNC, Reed Smith, Society for Corp. Gov., Sullivan, and ICI.

<sup>234</sup> The Commission did not propose similar amendments to Rule 0–6 because applications under the Investment Advisers Act filed pursuant to that rule are not required to be filed electronically. In addition, applications filed pursuant to Rule 0–6 may incorporate information that may not be filed on EDGAR.

<sup>235</sup> 17 CFR 239.40.

<sup>236</sup> See *Exhibit Hyperlinks Adopting Release*, *supra* note 10, at 14130.

<sup>237</sup> See *id.* at 14130. The rules adopted by the Commission at that time did not generally apply to investment companies. However, as discussed below, we are adopting similar requirements to certain filings by investment companies in this release. See *infra* Section II.B.7.b.

<sup>238</sup> See letters from CAQ, Davis Polk, E&Y, Fenwick, Grant Thornton, Grumman, KPMG, Piercy Bowler, Public Citizen, Reed Smith, Society for Corp. Gov., ICI, and Morningstar, Inc. (“Morningstar”).

<sup>239</sup> See letters from Davis Polk and E&Y.

clear that incorporating only a portion of a document filed on EDGAR is permissible,<sup>240</sup> while another commenter recommended that the Commission provide instructions for registrants to clarify which hyperlinks and cross-references relate to information incorporated by reference in the current filing and which are provided only for reader convenience and navigability.<sup>241</sup> Other commenters thought the Commission should consider allowing exceptions to the rule in certain situations.<sup>242</sup> Specifically, one commenter believed hyperlinks to Forms 10-K, 10-Q, and 8-K and definitive proxy statements should not be required, as they can be easily located by investors.<sup>243</sup> Another commenter believed hyperlinks should not be required in filings that also incorporated by reference to subsequently filed documents.<sup>244</sup> In addition, another commenter suggested that the Commission allow registrants and the staff to develop more experience with the recently adopted exhibit hyperlinking requirements prior to requiring additional hyperlinking.<sup>245</sup>

We are adopting the amendments to Rule 411, Rule 12b-23, and Rule 0-4 as proposed. By requiring an active hyperlink to information on EDGAR if it has been incorporated by reference into a registration statement or prospectus, we believe these amendments will improve the readability and navigability of disclosure documents and discourage repetition, consistent with our FAST Act mandate.

We do not believe that additional clarification in the new rules regarding the ability to incorporate portions of a previous filing by reference is necessary because existing rules regarding incorporation by reference already allow for this, and the new hyperlinking requirement does not change the substance of these rules.<sup>246</sup> Nor have we excluded hyperlinks to Forms 10-K, 10-Q, 8-K and definitive proxy statements

when those forms are incorporated by reference, as suggested by one commenter.<sup>247</sup> Such a restriction would reduce investors' ease of access to information and, therefore, the utility of the amendments. Moreover, as this commenter noted, the requirement is not anticipated to be a significant compliance burden for registrants.

With respect to one commenter's suggestion that we provide an exception to the hyperlinking requirement where a registration statement incorporates by reference subsequently filed documents,<sup>248</sup> we do not believe that this circumstance warrants a change to the rule. In the case of a shelf registration statement on Form S-3, for example, while it is correct that documents incorporated by reference under Item 12 of that form may become stale over time, the item requires the registrant to clearly state that the prospectus also incorporates by reference "all documents subsequently filed under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering." Accordingly, we do not believe that the existence of hyperlinks to the previously filed information will cause confusion among investors regarding the scope of information incorporated by reference or cause investors to disregard subsequently filed reports.

We are also not adopting instructions, as suggested by one commenter, which would require registrants to differentiate between hyperlinked information incorporated by reference in the current filing and hyperlinks provided only for reader convenience and navigability.<sup>249</sup> The new rules are solely meant to introduce a navigation feature and do not impose additional or modified requirements regarding what information may be incorporated by reference.

Finally, we are not delaying compliance with the new hyperlinking requirements, as suggested by one commenter, in the case of operating companies.<sup>250</sup> Delaying compliance seems unnecessary given that the exhibit hyperlinking rules have been in effect for all operating companies since September 1, 2018 and our amendments in this rulemaking are only incremental to the current rules.<sup>251</sup> Technologically, these new amendments requiring hyperlinks for information incorporated by reference are no different than

existing hyperlink disclosure requirements. Therefore, we anticipate any additional compliance burden for operating companies will not be significant. However, as outlined below in Section V.2, we are adopting a transition period for investment companies that is intended to provide them with time to prepare filings to include hyperlinks to exhibits and to information incorporated by reference, as well as help mitigate the cost burdens related to switching to HTML format for investment companies currently submitting filings in ASCII.

Under the amendments we are adopting, registrants are not required to file an amendment to a document solely to correct an inaccurate hyperlink, unless that hyperlink was included in a pre-effective registration statement, similar to the existing requirements for exhibit hyperlinking. An inaccurate hyperlink alone would neither render the filing materially deficient nor affect a registrant's eligibility to use Form S-3, Form SF-3, or Form F-3. In addition, registrants are not required to refile information that is incorporated by reference from a document that was previously filed with the Commission in paper. Similar to the Commission's reasoning in the Exhibit Hyperlinks Adopting Release, we believe such a requirement would have limited utility given that electronic filing has been required for over two decades and paper filings are currently made in very limited circumstances.<sup>252</sup>

Unlike the requirements for exhibit hyperlinking, however, a registrant is not required to correct inaccurate hyperlinks to information incorporated by reference in an effective registration statement by including a corrected hyperlink in a subsequent periodic report or a post-effective amendment. We believe that it would result in more confusion than clarity if we were to require registrants to re-file disclosure to correct a hyperlink or to include a section solely devoted to corrected hyperlinks in the body of a periodic report or post-effective amendment. This differs from exhibit hyperlinks where the corrected hyperlink would be unobtrusively located in the exhibit index with other exhibits. The requirement in amended Rule 411, Rule 12b-23, and Rule 0-4 to describe the location of the information incorporated by reference should mitigate the impact of any inaccurate hyperlinks.

<sup>252</sup> See Exhibit Hyperlinks Adopting Release, *supra* note 10, at 14131. See also FAST Act Report, *supra* note 7, at n. 31 and accompanying text.

<sup>240</sup> See letter from Davis Polk.

<sup>241</sup> See letter from E&Y (noting that this clarification would benefit the PCAOB's work regarding the scope of an auditor's responsibility for information in a filing subject to the requirements of AS 2710, *Other Information in Documents Containing Audited Financial Statements*).

<sup>242</sup> See letters from Fenwick and Reed Smith.

<sup>243</sup> See letter from Fenwick.

<sup>244</sup> See letter from Reed Smith (stating that the use of hyperlinks, particularly in connection with shelf registration statements, could direct readers to stale or superseded information).

<sup>245</sup> See letter from Cravath.

<sup>246</sup> See Securities Act Rule 411 and Exchange Act Rule 12b-23, which state that "where only certain pages of a document are incorporated by reference . . . , the document from which the [information or material] is taken shall be clearly identified in the reference."

<sup>247</sup> See letter from Fenwick.

<sup>248</sup> See letter from Reed Smith.

<sup>249</sup> See letter from E&Y.

<sup>250</sup> See letter from Cravath.

<sup>251</sup> See Exhibit Hyperlinks Adopting Release, *supra* note 10.

### iii. Other Amendments

As discussed in detail in the Proposing Release, the Commission proposed several non-substantive changes to Rule 411, Rule 12b-23, Rule 0-4, and Rule 0-6 to streamline, clarify, and conform these rules.<sup>253</sup>

Several commenters supported the proposal, and no commenters opposed.<sup>254</sup> For the reasons noted in the Proposing Release, we are adopting the proposed amendments to Rule 411, Rule 12b-23, Rule 12b-32, Rule 0-4, and Rule 0-6, as proposed.

## 7. Manner of Delivery

### a. Tagging Cover Page Data

Currently, operating company registrants<sup>255</sup> are required to file their financial statements as an exhibit in a machine-readable format using eXtensible Business Reporting Language (“XBRL”).<sup>256</sup> This disclosure is required as an exhibit to periodic reports and Securities Act registration statements, as well as reports on Form 8-K or Form 6-K that contain revised or updated financial statements. The Commission recently adopted rules requiring the use of Inline XBRL format, where XBRL data is embedded into the HTML document, instead of the traditional XBRL format<sup>257</sup> for the submission of

<sup>253</sup> See Proposing Release, *supra* note 5, Section II.F.2.d. at 51011-2.

<sup>254</sup> See letters from American Fuel, CAQ, CCMC, Cravath, Davis Polk, E&Y, Fenwick, Piercy Bowler, PNC, Reed Smith, Society for Corp. Gov., and Sullivan.

<sup>255</sup> As used in this context, operating companies do not include any investment company that is registered under the Investment Company Act, any business development company, as defined in Section 2(a)(48) of that Act [15 U.S.C. 80a-2(a)(48)], any entity that reports under the Exchange Act and prepares its financial statements in accordance with Article 6 of Regulation S-X [17 CFR 210.6-01 through 210.6-10], or asset-backed issuers. See *Interactive Data to Improve Financial Reporting*, Release No. 33-9002 (Jan. 30, 2009) [74 FR 6776 (Feb. 10, 2009)], as corrected by Release No. 33-9002A (Apr. 1, 2009) [74 FR 15666 (Apr. 7, 2009)] (the “XBRL Adopting Release”), at 6780-1, nn. 69 and 78 and accompanying text.

<sup>256</sup> For domestic disclosure forms, the XBRL data-tagging requirements are imposed through Item 601(b)(101) of Regulation S-K and Rule 405(b) of Regulation S-T. See Item 601(b)(101) of Regulation S-K and Rule 405(b) of Regulation S-T [17 CFR 232.405(b)]. For foreign disclosure forms, analogous XBRL tagging requirements are included in the instructions to the relevant forms. See, e.g., paragraphs 100 and 101 of the Instructions to Exhibits to Form 20-F. XBRL data-tagging requirements do not apply to asset-backed securities filings because issuer financial statements are generally not required or provided in filings made pursuant to Regulation AB [17 CFR 229.1100 *et seq.*]. See the XBRL Adopting Release, *supra* note 255, at n. 78.

<sup>257</sup> In the traditional XBRL format for financial statements, which will be phased out as operating companies transition to Inline XBRL, as discussed *infra* at note 258, none of the registrant’s XBRL data is embedded into an HTML document. Instead, an

operating company financial statements and risk/return summary information for open-end management investment companies.<sup>258</sup>

Registrants must also tag in XBRL a specific group of data points that appears on the cover page of the filing. These specific data points, which are tagged according to Regulation S-T and the EDGAR Filer Manual, are known as document and entity identifier elements and include, among others, form type, company name, filer size, and public float.<sup>259</sup> This information corresponds to some, but not all, of the information that registrants are required to include on the filing cover page. For example, the Form 10-K cover page contains approximately 25 data points. Less than half of those data points are currently required to be tagged in XBRL. The non-tagged data points include, among others, the exchange on which securities are registered and the state (or jurisdiction) of incorporation.

The Commission proposed amendments to require all of the information on the cover pages of Form 10-K, Form 10-Q, Form 8-K, Form 20-F, and Form 40-F to be tagged in Inline XBRL in accordance with the EDGAR Filer Manual.<sup>260</sup> To implement the cover page tagging requirements, the Commission also proposed to add new Rule 406 to Regulation S-T, new Item 601(b)(104) to Regulation S-K, new paragraph 104 to the “Instructions as to Exhibits” of Form 20-F, and new paragraph B.17 to the “General Instructions” of Form 40-F to require registrants to file with each of the specified forms a “Cover Page Interactive Data File.”<sup>261</sup> The

exhibit containing all XBRL data is filed with the relevant form. Inline XBRL allows filers to embed XBRL data directly into an HTML document, eliminating the need to tag a copy of the information in a separate document.

<sup>258</sup> See *Inline XBRL Filing of Tagged Data*, Release No. 33-10514 (June 28, 2018) [83 FR 40846 (July 10, 2018)] (“Inline XBRL Adopting Release”). Operating companies that are currently required to submit financial statement information in XBRL and open-end management investment companies that are currently required to submit risk/return summary XBRL data will be required, on a phased-in basis, to transition to Inline XBRL. The date of mandatory compliance with the Inline XBRL rules depends on the type of filer. See Section III.A.1.c. of the Inline XBRL Adopting Release.

<sup>259</sup> See Rule 405 of Regulation S-T [17 CFR 232.405]; See also XBRL Adopting Release (discussing the requirement to tag document and entity identifier elements, such as form type, company name, and public float, according to Regulation S-T and the EDGAR Filer Manual).

<sup>260</sup> See Proposing Release, *supra* note 5, Section II.G.1. at 51013-4.

<sup>261</sup> The Commission proposed that registrants filing Form 20-F and Form 40-F would be required to tag cover page data only when those forms are used as annual reports, not as registration statements. See Proposing Release, *supra* note 5, at 51014.

Commission also proposed to revise Rule 11 of Regulation S-T to add the term “Cover Page Interactive Data File.” The term would be defined as the machine readable computer code that presents the information required by Rule 406 of Regulation S-T in Inline XBRL format.

In addition, the Commission proposed amendments to the cover pages of these forms to include the trading symbol for each class of registered securities.<sup>262</sup> Because the cover pages of Form 10-K, Form 20-F, and Form 40-F already require disclosure of the title of each class of securities registered pursuant to Section 12(b) of the Exchange Act and each exchange on which they are registered, the Commission proposed amendments to these forms that would revise the cover page to include a corresponding field for the trading symbol. Unlike Form 10-K, Form 20-F, and Form 40-F, however, the cover pages of Form 10-Q and Form 8-K do not currently require disclosure of the title of each class of securities and each exchange on which they are registered. Accordingly, to ensure that registrants and their registered securities are identified in a consistent manner across forms, the Commission proposed to revise the cover pages of Form 10-Q and Form 8-K to include this disclosure in addition to the trading symbol.

Commenters were divided in their responses to the proposal. Several commenters believed that tagging cover page data would be useful and viewed XBRL generally as a benefit to investors in collecting and analyzing financial information.<sup>263</sup> Some commenters further recommended expanding the proposal to require that additional information be tagged.<sup>264</sup> By contrast, a

<sup>262</sup> In the Disclosure Update and Simplification Release, the Commission amended Item 201(a) to also require disclosure of the trading symbol(s) for each class of a registrant’s common equity. See Disclosure Update and Simplification Release, *supra* note 147, at Section IV.C.1.(a).

<sup>263</sup> See letters from Calcbench, Inc. (“Calcbench”), Grumman, Merrill Corporation (“Merrill”), Morningstar, and XBRL US, Inc. (“XBRL US”).

<sup>264</sup> See, e.g., letters from Calcbench (supporting the expansion of XBRL tagging to MD&A), Merrill (recommending extending the proposed tagging requirements to Form 6-K), and XBRL US (recommending requiring XBRL tagging of additional forms, such as the Form 8-K earnings report). *But see* letter from Grumman (recommending that the proposal not be extended to MD&A, earnings releases, or proxy statements because the costs of compliance would outweigh the benefits). In the Proposing Release, the Commission asked whether there were any additional disclosures discussed in the release that should be required in machine-readable structured format, such as within Item 303(a) or any property disclosures under Item 102. See Proposing Release, *supra* note 5, at 51014. We are not adopting these

number of other commenters opposed the proposal, and were skeptical that the benefit of tagging cover page data justified the costs of compliance.<sup>265</sup> Noting their concerns over the burdens already incurred by registrants to satisfy existing data-tagging obligations, some commenters urged that studies be undertaken to assess investor usage of XBRL information before expanding XBRL requirements any further.<sup>266</sup>

After considering the comments, we are adopting the amendments as proposed.<sup>267</sup> By increasing the capacity for automation of the data gathering process, we believe these amendments will further enhance investors' use of interactive data to identify, count, sort, compare, and analyze registrants and their disclosures.<sup>268</sup> For example, an investor will be able to more readily and accurately identify registrants that are listed on a specific exchange and that identified themselves as well known seasoned issuers in their last annual report. Similarly, the Inline XBRL tagging of the new ticker symbol disclosure requirement will make it easier to relate/link a specific security to the underlying registrant. In addition, the amendments will allow the Commission to make enhancements to the EDGAR system to enable investors to search for filings with these specific criteria. The new filing requirements will also be of benefit to the Commission, as the Commission and its staff will be able to more readily sort and analyze filings to, among other things, improve data and analysis for rulemaking initiatives.

We do not expect the incremental compliance burden associated with

additional tagging requirements at this time, several of which are beyond the scope of this rulemaking.

<sup>265</sup> See letters from CCMC, FedEx, Financial Executives, IMA, Society for Corp. Gov., and UnitedHealth.

<sup>266</sup> See letter from CCMC and IMA. We note that the Inline XBRL Adopting Release included a discussion of current XBRL usage levels indicating "a wide range of XBRL data users, including investors, financial analysts, economic research firms, data aggregators, academic researchers, filers seeking information on their peers for benchmarking purposes, and Commission staff." See Inline XBRL Adopting Release, *supra* note 258, at 40850.

<sup>267</sup> As proposed, the amendments apply to Form 20-F or Form 40-F only when those forms are used as annual reports, not registration statements. See new paragraph 104 to Instructions as to Exhibits of Form 20-F and new paragraph B.17 of General Instructions to Form 40-F.

<sup>268</sup> See the Recommendations of the Investor Advisory Committee Regarding the SEC and the Need for the Cost Effective Retrieval of Information by Investors (Jul. 25, 2013), available at <http://www.sec.gov/spotlight/investor-advisory-committee-2012/data-tagging-resolution-72513.pdf> (recommending, among other things, that the Commission promote the use of machine-readable data tagging formats in filings with the Commission).

tagging the additional cover page information to be significant, given that registrants already are required to tag some of this information as well as information in their financial statements. The amendments will also facilitate future enhancements to the EDGAR system by utilizing the tagged information to reduce duplicative entry of information into both the filing and the submission header at the time of filing.

#### b. Exhibit Hyperlinks and HTML Format for Investment Companies

As discussed above, the Commission recently adopted rules requiring hyperlinks to most exhibits filed pursuant to Item 601, Form F-10, and Form 20-F, and, to accommodate hyperlinking, those filings are required to be made in HTML.<sup>269</sup> The Commission proposed parallel amendments to Regulation S-T Rules 102 and 105 and certain of our registration and reporting forms that are used by investment companies that would apply similar exhibit hyperlinking and HTML submission requirements in those forms to facilitate access to exhibits by investors and other users of the information. Specifically, the proposed amendments would require an investment company filing a registration statement on Forms S-6, N-1A, N-2, N-3, N-4, N-5, N-6, and N-14, or reports on Form N-CSR, to include a hyperlink to each exhibit identified in that filing's exhibit index, unless the exhibit is filed in paper pursuant to an exemption under Rule 201, Rule 202, or Rule 311 of Regulation S-T.

One commenter supported the proposed amendments to require exhibit hyperlinks and associated HTML submission requirements, stating that it would help investors' ability to navigate through EDGAR filings and advance investor protection.<sup>270</sup> Another commenter requested clarification on how the proposed HTML submission requirement would affect filers on Form N-4 and Form N-6 who use type 1 modules under EDGARLink<sup>271</sup> to make these submissions because the type 1 modules are only supported by ASCII, and not HTML.<sup>272</sup>

<sup>269</sup> See Exhibit Hyperlinks Adopting Release, *supra* note 10, at 14130.

<sup>270</sup> See letter from ICI.

<sup>271</sup> EDGARLink is an application that is used by electronic filers to facilitate the preparation, validation, and transmission of electronic format documents to EDGAR. EDGARLink works interactively with EDGAR and is available for download from the Commission's website.

<sup>272</sup> See letter from G. Stanzione. Modules are partial or complete documents that are intended to be included in an electronic submission. In

After considering the comments, we are requiring, as proposed, investment companies filing registration statements on Forms S-6, N-14, N-5, N-1A, N-2, N-3, N-4, N-6, and reports on Form N-CSR, to include a hyperlink to each exhibit (other than an exhibit filed in XBRL) identified in the filing's exhibit index, unless the exhibit is filed in paper pursuant to a temporary or continuing hardship exemption under Rule 201 or Rule 202 of Regulation S-T, or pursuant to Rule 311 of Regulation S-T.<sup>273</sup> In addition, we are extending similar exhibit hyperlinking and HTML filing requirements to filings on Form N-8B-2.<sup>274</sup> Consistent with our rules for operating companies, we are not requiring investment companies to refile electronically any exhibits previously filed in paper.<sup>275</sup>

A registered investment company will be required to correct an inaccurate or nonfunctioning link or hyperlink to an exhibit as follows. In the case of a registration statement that is not yet effective, the filer will be required to file an amendment to the registration statement containing the inaccurate or nonfunctioning link or hyperlink. In the case of a registration statement that has become effective, the filer will be required to correct an inaccurate or nonfunctioning link or hyperlink in the next post-effective amendment, if any, to the registration statement.<sup>276</sup> In the case of a report on Form N-CSR, the filer will be required to correct the inaccurate or nonfunctioning link or

connection with our ongoing efforts to upgrade EDGAR, we are updating type 1 and type 2 modules to permit their use in connection with filings made in HTML. These updates are expected to be completed by June 2019.

<sup>273</sup> See Rule 102(d); Rule 105(d) of Regulation S-T.

<sup>274</sup> Form N-8B-2 is the form used by unit investment trusts other than separate accounts that are currently issuing securities to register under the Investment Company Act. The form requires the registration statement to include exhibits similar to those required under the Commission's other investment company registration forms. We believe extending similar exhibit hyperlinking and HTML filing requirements to filings on Form N-8B-2 would further achieve our objective of facilitating access to exhibits by investors and other users of the information.

<sup>275</sup> See Instruction 1 to paragraph (d) of Rule 105.

<sup>276</sup> See Instruction 2 to paragraph (d) of Rule 105. We proposed to amend Instruction 2 to paragraph (d) of Rule 105 to include a new provision pertaining to an investment company registration statement that has become effective that contains an inaccurate or nonfunctioning link or hyperlink. That new provision would have required the filer to correct the link or hyperlink in the next post-effective amendment, if any, to the registration statement. We are not adopting the proposed amendment because the provision would be duplicative of the current provision of Instruction 2 to paragraph (d) of Rule 105.

hyperlink in its next report on Form N-CSR.

In connection with the exhibit hyperlinking requirements, we are also adopting an amendment to Regulation S-T Rule 105 to require filings on Forms S-6, N-14, N-5, N-1A, N-2, N-3, N-4, N-6, N-8B-2, and N-CSR be submitted in HTML format. Prior to this amendment, electronic filers were permitted to submit such filings in either the ASCII format or HTML format. Because the ASCII format does not support hyperlink functionality, the exhibit hyperlinking requirement is feasible only if documents are filed in HTML. Accordingly, electronic filers will now be required to file registration statements and reports on Form N-CSR (and any amendments thereto) in HTML format.<sup>277</sup>

### C. Proposed Amendments Not Being Adopted

#### 1. Forms—Captions and Item Numbers

The Commission proposed amendments to Form 10, Form 10-K, and Form 20-F to allow registrants to exclude item numbers and captions or to create their own captions tailored to their disclosure.<sup>278</sup> The proposed amendments did not affect captions that are expressly required by the forms or Regulation S-K.<sup>279</sup> The proposed amendments were intended to reduce the use of unnecessary cross-references when information may be responsive to more than one disclosure item in the Exchange Act forms. The Commission stated its belief that increasing flexibility in this manner may reduce repetitive disclosure or unnecessary cross-references when information may be responsive to more than one item and thereby enhance the overall readability of required disclosures.

Of the commenters who addressed the issue, a majority opposed the proposal to amend Form 10, Form 10-K, and Form 20-F to eliminate the requirements to include most item

numbers and captions.<sup>280</sup> While they supported the Commission's intent to allow registrants greater flexibility over the presentation of their disclosure, these commenters cautioned that this change could make an investor's task more challenging. Commenters suggested that the required captions and item numbers help investors navigate filings, make it more easy to locate information important to them, and enhance their ability to compare information in different filings.

In light of these comments, we have decided not to adopt the proposed changes to the item number and caption requirements of Form 10, Form 10-K, and Form 20-F. Upon further review, we believe that any potential benefits from the amendments that would accrue to registrants and investors by permitting more variability in the presentation of disclosure could be outweighed by the risk that the changes could impair an investor's ability to use and navigate the information efficiently and effectively.

#### 2. Subsidiaries of the Registrant and Entity Identifiers

Item 601(b)(21)(i) requires a registrant to list as an exhibit all of its subsidiaries, the state or other jurisdiction of incorporation or organization of each, and the names under which those subsidiaries do business.<sup>281</sup> The Commission proposed amendments to Item 601(b)(21)(i) that would require registrants to also include in the exhibit the legal entity identifier ("LEI"), if one has been obtained, of the registrant and each subsidiary listed.

Comments on the proposal were mixed. Commenters who were in favor of the proposal<sup>282</sup> generally stated that LEIs will make it easier for investors, analysts, and regulators to understand relationships between interrelated companies and more accurately assess investment risk.<sup>283</sup> Several commenters, however, expressed doubts about the benefits of the information<sup>284</sup> or were concerned that it would be costly and time consuming to acquire and maintain LEIs, particularly for registrants with

numerous subsidiaries or affiliates operating globally.<sup>285</sup> In light of these comments, we have decided not to adopt the amendments to Item 601(b)(21)(i) as proposed.

### D. Removal of Outdated Requirement

Rule 312 of Regulation S-T permitted issuers of asset-backed securities, for their filings filed on or before June 30, 2012, to post static pool disclosures on an internet website under certain conditions in lieu of filing the information on EDGAR. This temporary accommodation lapsed on June 30, 2012, and in 2014, in the adopting release for revisions to disclosure requirements for asset-backed securities, the Commission reiterated that issuers are no longer able to use Rule 312 as a means to provide their static pool information.<sup>286</sup> As stated in that release, the Commission did not remove Rule 312 at that time since asset-backed issuers that previously provided static pool information via a website were required to retain all versions of the information provided through the website for a period of not less than five years. Because the period for retention has now lapsed, the rule has become obsolete due to the passage of time, and therefore we are removing Rule 312 from Regulation S-T.<sup>287</sup>

### III. Other Matters

If any of the provisions of these rules, or the application thereof to any person or circumstance, is held to be invalid, such invalidity shall not affect other provisions or application of such provisions to other persons or circumstances that can be given effect without the invalid provision or application.

Section 553(d) of the Administrative Procedure Act generally requires an agency to publish an adopted rule in the **Federal Register** 30 days before it becomes effective.<sup>288</sup> This requirement does not apply, however, if the adopted rule is a "substantive rule which grants or recognizes an exemption or relieves a restriction."<sup>289</sup> We find that our amendments to the rules governing redaction of confidential information in material contracts, discussed in Section II.A.2. above, are substantive rules that

<sup>277</sup> See amendments to Regulation S-T Rule 105(d). While the affected registration statements and reports will be required to be filed in HTML pursuant to the amendments to S-T Rule 105, registrants will continue to be permitted to file in ASCII any schedules or forms that are not subject to the exhibit filing requirements, such as proxy statements, or other documents included with a filing, such as an exhibit.

<sup>278</sup> Rule 12b-13 requires registrants to include the numbers and captions of all items in these forms. Although provisions in a form control when they cover the same subject matter as a rule in Regulation 12B, these forms do not contradict Rule 12b-13.

<sup>279</sup> For example, Form 10-K and Form 20-F require captions for "audit fees," "audit-related fees," "tax fees," and "all other fees." Regulation S-K requires a caption for "risk factors."

<sup>280</sup> See, e.g., letters from Fenwick and Reed Smith. *But see* letter from E&Y (supporting the proposal for providing registrants more flexibility in organizing disclosures and tailoring their presentation).

<sup>281</sup> Item 601(b)(21)(i) of Regulation S-K [17 CFR 229.601(b)(21)(i)].

<sup>282</sup> See letters from CII, The FACT Coalition, Merrill, Morningstar, and XBRL US.

<sup>283</sup> See, e.g., letters from CII, Morningstar, and XBRL US.

<sup>284</sup> See, e.g., letters from Cravath, Financial Executives (indicating that such rules may not be necessary outside the financial services industry), IMA, and UnitedHealth.

<sup>285</sup> See letter from Financial Executive. *See also* letters from Ball and CCMC.

<sup>286</sup> See *Asset-Backed Securities Disclosure and Registration*, Release No. 33-9638 (Sept. 4, 2014) [79 FR 57184 at 57258].

<sup>287</sup> We find that there is good cause to adopt the amendment without notice and comment. Because the amendment makes a technical change to eliminate an obsolete provision, notice and comment are unnecessary. *See* 5 U.S.C. 553(b)(B).

<sup>288</sup> *See* 5 U.S.C. 553(d).

<sup>289</sup> *See* 5 U.S.C. 553(d)(1).

relieve a restriction. Specifically, these amendments relieve registrants of the requirement to prepare and process confidential treatment requests for information in their material contracts filed as exhibits, so long as the information is not material and is likely to cause competitive harm to the registrant if publicly disclosed.<sup>290</sup> Accordingly, the following provisions are effective April 2, 2019: Amendments to Items 601(b)(2)(ii) and 601(b)(10)(iv) of Regulation S-K; paragraph 4(a) of Instructions as to Exhibits of Form 20-F; Instruction 6 to Item 1.01 of Form 8-K; new Instruction 4 to Item 28 of Form N-1A; new Instruction 6 to Item 25.2 of Form N-2; new Instruction 5 to Item 29(b) of Form N-3; new Instruction 5 to Item 24(b) of N-4; new Instruction 3 of Instructions as to Exhibits of Form N-5; new Instruction 3 to Item 26 of Form N-6; new Instruction 3 to Item 16 of Form N-14; new Additional Instruction 3 to the Instructions as to Exhibits of Form S-6; and new Instruction 3 to IX. Exhibits of Form N-8B-2.<sup>291</sup>

#### IV. Transition Matters

If a registrant has a confidential treatment request pending at the time the amended rules governing redaction of confidential information in material contracts become effective, the registrant may, but is not required to, withdraw its pending application. The Commission and its staff will continue to process pending CTR applications that are not withdrawn, following established procedures. Registrants who opt to withdraw their CTR applications in order to rely on the amended rules are advised to refile the exhibit or exhibits, in redacted form, in an amended filing with the Commission that conforms to the amended rules. Registrants should contact the Assistant Director office, or in the case of an investment company the Division of Investment Management's Disclosure Review and Accounting Office, responsible for reviewing their filings to coordinate the withdrawal of any confidential treatment application and the re-filing of the exhibit or exhibits.

#### V. Compliance Dates

Except as noted above in Section III (Other Matters) and below, registrants will be required to comply with these amendments beginning May 2, 2019.

##### A. Tagging of Cover Page Data

We are adopting phased compliance dates for the requirements to tag data on

the cover pages of Form 10-K, Form 10-Q, Form 8-K, Form 20-F, and Form 40-F in Inline XBRL. To mitigate the potential burden associated with the transition of filers and preparers to Inline XBRL generally, these dates are identical to the compliance dates for mandatory compliance with the Inline XBRL rules set forth in the Inline XBRL Adopting Release.<sup>292</sup> The date of compliance depends on the type of filer, as follows:

Operating companies	Compliance date <sup>293</sup>
Large accelerated filers that prepare their financial statements in accordance with U.S. GAAP.	Reports for fiscal periods ending on or after June 15, 2019.
Accelerated filers that prepare their financial statements in accordance with U.S. GAAP.	Reports for fiscal periods ending on or after June 15, 2020.
All other filers .....	Reports for fiscal periods ending on or after June 15, 2021.

As illustrated, we are adopting a three-year phase-in whereby: (i) Large accelerated filers that prepare their financial statements in accordance with U.S. GAAP will be required to comply with the cover page tagging requirements in reports for fiscal periods ending on or after June 15, 2019; (ii) accelerated filers that prepare their financial statements in accordance with U.S. GAAP will be required to comply in reports for fiscal periods ending on or after June 15, 2020; and (iii) all other filers that are subject to the cover page tagging requirements, including foreign private issuers that prepare their financial statements in accordance with IFRS, will be required to comply in reports for fiscal periods ending on or after June 15, 2021. Domestic form filers<sup>294</sup> will be required to comply beginning with their first Form 10-Q for a fiscal period ending on or after the applicable compliance date, as opposed to the first filing for a fiscal period ending on or after that date.<sup>295</sup>

<sup>292</sup> See *supra* note 258.

<sup>293</sup> Form 10-Q filers will not become subject to the Inline XBRL requirements with respect to Form 10-K or any other form until after they have been required to comply with the Inline XBRL requirements for their first Form 10-Q for a fiscal period ending on or after the applicable compliance date for the respective category of filers.

<sup>294</sup> Form 20-F and 40-F filers do not have quarterly report filing obligations and are therefore not affected by this provision.

<sup>295</sup> As an example, a Form 10-Q filer in the first phase-in group with a calendar fiscal year end will be required to begin compliance with its Form 10-Q for the period ending June 30, 2019. As a further

To be consistent with existing Inline XBRL data-tagging requirements, these cover page tagging requirements only apply to electronic filers that file the specified forms and who are required to submit Interactive Data Files in Inline XBRL format under Regulation S-T.<sup>296</sup> Therefore, the requirements do not apply to non-operating companies such as any investment companies registered under the Investment Company Act, business development companies, as defined in Section 2(a)(48) of that Act,<sup>297</sup> entities that report under the Exchange Act and prepare their financial statements in accordance with Article 6 of Regulation S-X,<sup>298</sup> or asset-backed issuers.

##### B. Hyperlinks and HTML Format for Investment Companies

We are adopting a transition period that is intended to provide investment company registrants time to prepare filings to include hyperlinks to exhibits and to information incorporated by reference, as well as help mitigate the cost burdens related to switching over to HTML format for registrants currently submitting filings in ASCII. All registration statement and Form N-CSR filings made on or after April 1, 2020 must be made in HTML format and comply with the rule and form amendments pertaining to the use of hyperlinks. However, we welcome early compliance with the new filing requirements.

#### VI. Economic Analysis

We are sensitive to the economic effects that may result from the amendments. Securities Act Section 2(b),<sup>299</sup> Exchange Act Section 3(f),<sup>300</sup> and Investment Company Act Section 2(c)<sup>301</sup> require us, when engaging in rulemaking that requires us to consider or determine whether an action is necessary or appropriate in (or, with respect to the Investment Company Act, consistent with) the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. Additionally, Exchange Act Section 23(a)(2)<sup>302</sup> requires us, when adopting rules and

example, a Form 10-Q filer in the first phase-in group with a June 30 fiscal year end will be required to begin compliance with its Form 10-Q for the period ending September 30, 2019.

<sup>296</sup> See new Rule 406 of Regulation S-T [17 CFR 232.406].

<sup>297</sup> 15 U.S.C. 80a-2(a)(48).

<sup>298</sup> 17 CFR 210.6-01 through 210.6-10.

<sup>299</sup> 5 U.S.C. 77b(b).

<sup>300</sup> 15 U.S.C. 78c(f).

<sup>301</sup> 15 U.S.C. 80a-2(c).

<sup>302</sup> 15 U.S.C. 78w(a)(2).

<sup>290</sup> See *supra* Section II.A.2.c.

<sup>291</sup> But see *infra* Section V.B. for a discussion of the compliance dates for the HTML filing and exhibit hyperlinking requirements.

amendments under the Exchange Act, to consider the impact that any new rule will have on competition and not to adopt any rule or amendment that will impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The expected economic effects of the amendments, as well as possible alternatives to the amendments, are discussed in detail below. Where possible, we have sought to quantify the benefits, costs, and effects on efficiency, competition, and capital formation expected to result from the amendments. However, we are unable to reliably quantify many of the economic effects due to limitations on available data. Therefore, parts of the discussion below are qualitative in nature, although we try to describe, where possible, the direction of these effects.

A disclosure regime that facilitates the disclosure of material, reliable information can reduce informational asymmetries between managers of companies and investors, which can enhance capital formation and the allocative efficiency of the capital markets. At the same time, there are potential drawbacks associated with disclosure requirements. For example,

disclosure can be costly for registrants to produce and disclosure of sensitive information can result in competitive disadvantages. These general considerations help to frame our analysis of the potential economic effects of the amendments, as discussed in detail below.<sup>303</sup>

In the economic analysis that follows, we first examine the current regulatory and economic landscape that forms the baseline for our analysis. We then analyze the likely economic effects arising from the rule amendments relative to that baseline. These economic effects include the costs and benefits and impact on efficiency, competition, and capital formation.

*A. Baseline*

To assess the economic effect of the amendments, we are using as our baseline the current state of the Commission's filing and disclosure regime. In characterizing the baseline, it is useful to distinguish between operating companies and investment companies. Although both types of registrants are subject to registration and reporting requirements, there are differences in the specific rules and forms applicable to each. In particular, on March 1, 2017, the Commission

adopted amendments requiring registrants that file registration statements and reports subject to the exhibit requirements under Item 601 of Regulation S-K or that file Form F-10 or Form 20-F (*i.e.*, operating companies) to submit these filings in HTML format and to include a hyperlink to each exhibit listed in the exhibit index of these filings. In contrast, there is currently no comparable requirement for investment companies.

For operating companies, the baseline includes the disclosure requirements in Regulation S-K and related rules and forms as well as existing guidance on the application of those requirements. Table 1 below suggests that the amendments to Regulation S-K and related rules and forms will apply to a substantial number of operating companies. On average, about 7,400 different registrants per year have filed periodic reports on Form 10-K and Form 10-Q in recent years. As shown in the table below, approximately 800 foreign private issuers provided periodic information to investors in the U.S. capital markets using Form 20-F and Form 40-F. The number of registrants filing definitive proxy statements on Schedule 14A has exceeded 5,000 each year.<sup>304</sup>

TABLE 1—NUMBER OF REGISTRANTS FILING VARIOUS DISCLOSURE FORMS FROM 2014–2018

Year	10-K	10-Q	20-F	40-F	DEF 14A
2014	7,857	7,872	669	143	5,259
2015	7,767	7,676	687	131	5,390
2016	7,373	7,147	675	126	5,126
2017	7,074	6,816	658	129	5,104
2018	6,907	6,549	679	127	5,063

As discussed above, investment companies making filings on certain forms required by the Commission will also be affected by the amendments. Table 2 below lists the number of filings filed by investment companies in calendar year 2018 using EDGAR submission types potentially affected by the amendments, broken out by the number of filings in HTML and ASCII format. From January 1, 2018 to December 31, 2018, investment companies filed 64,470 filings using EDGAR submission types potentially affected by the amendments. Of these filings, the vast majority (58,137) were filed in HTML, while 10% (6,333) were filed in ASCII format. As shown in Table 2, in 2018, more filings were made in HTML than ASCII format, with

the exception of filings on Form N-8B-2 and Form S-6 where more filings were made in ASCII than HTML format.

TABLE 2—NUMBER OF POTENTIALLY AFFECTED FILINGS FROM JANUARY 1, 2018 TO DECEMBER 31, 2018

	Number of HTML filings	Number of ASCII filings
N-1A	42,316	329
N-2	1,514	20
N-3	26	9
N-4	5,374	650
N-5	0	0
N-6	1,614	190
N-8B-2	1	3
N-14	271	0
N-CSR	6,575	134

TABLE 2—NUMBER OF POTENTIALLY AFFECTED FILINGS FROM JANUARY 1, 2018 TO DECEMBER 31, 2018—Continued

	Number of HTML filings	Number of ASCII filings
S-6	446	4,998
Total	58,137	6,333

The amendments will require registrants to include hyperlinks in the case of exhibits included with the forms and exhibits that are incorporated by reference from a previously filed document. To draw a baseline indicative of current disclosure practices, we selected a random sample

<sup>303</sup> See Proposing Release Section III.A. for detailed discussion of the benefits and costs of disclosure.

<sup>304</sup> We note that, in addition to operating companies, registered investment companies file proxy materials as well.

of 400 filings (347 in HTML and 53 in ASCII) submitted in 2017 that may be affected by the amendments. Table 3

below shows the average and median number of exhibits listed in the sampled filings by the type of exhibit (*i.e.*, filed

with the form vs. incorporated by reference).

TABLE 3—NUMBER OF EXHIBITS IN SAMPLED FILINGS<sup>305</sup>

	Number of exhibits listed in the index		Number of exhibits filed with the filing		Number of exhibits incorporated by reference		Number of sampled filings
	Average	Median	Average	Median	Average	Median	
	N-1A .....	34.8	0	2.1	0	32.8	
N-2 .....	20.9	24	4.9	3	16	12	7
N-3 .....	171.5	171.5	14	14	157.5	157.5	2
N-4 .....	58.2	37.5	3.1	3	55.1	35	24
N-5 .....	NA	NA	NA	NA	NA	NA	0
N-6 .....	183	183	14	14	169	169	1
N-8B-2 .....	NA	NA	NA	NA	NA	NA	0
N-14 .....	19.5	19.5	8.5	8.5	11	11	2
N-CSR .....	2.3	2	2.1	2	0.2	0	120
S-6 .....	6.8	8	2	2	4.8	4	41
All Filings .....	24.1	2	2.3	2	21.8	0	400

Table 3 shows significant variation in the number of exhibits listed in the exhibit index across different types of filings. Registration statements on Form N-3, Form N-4, and Form N-6 typically contain a large number of exhibits and had more exhibits incorporated by reference than filings on other forms affected by the amendments. Of the 400 sampled filings, we found that none of them included hyperlinked indexes.

Disclosure requirements involve trade-offs between benefits to investors in terms of reducing information asymmetries and costs to registrants associated with producing disclosure. While the amendments will apply to all registrants subject to the regulation, the trade-offs between the costs and benefits of disclosure requirements will vary across different types of registrants. For example, because many of the costs associated with disclosure do not vary with firm size, smaller companies may have higher disclosure costs in proportion to their revenues. Smaller companies also may have relatively

higher disclosure benefits.<sup>306</sup> While the fixed costs of disclosure requirements typically constitute a higher percentage of revenues for smaller companies than for larger companies, the benefits of disclosure may be greater for smaller companies because information asymmetries between investors and managers of smaller companies are typically higher than for larger companies. The costs of disclosure requirements can be also higher for foreign registrants to the extent that the disclosure requirements in the United States are different from the disclosure requirements in their home countries.

#### *B. Economic Analysis of the Amendments: General Assessment, Including Impact on Efficiency, Competition, and Capital Formation*

In this section, we evaluate the broad economic effects of the amendments, including a discussion of their impact on efficiency, competition, and capital formation. The amendments will discourage repetition and disclosure of information that is immaterial (*see, e.g.*,

amendments to Item 102 and Instruction 1 to Item 303(a)); will decrease investors' information processing costs (*see, e.g.*, Rule 411, Rule 12b-23, and Rule 0-4); and will decrease registrants' costs to prepare filing materials (*see, e.g.*, amendment to Item 601(b)(10)). The amendments modify a well-established and robust disclosure regime that has existed for many years. As a result, we expect the aggregate impact of the amendments (in the form of more accurate share prices, better accountability of managers, and increased capital market liquidity) to be incremental to the effects that have already been realized from the existing disclosure regime.

Disclosure provides benefits to participants in financial markets by reducing information asymmetries that exist between investors in a company and managers tasked with operating the company. Both registrants and investors alike should generally benefit from the amendments because they are designed to simplify the requirements and resulting content of existing disclosures while still providing all material information. We believe that changes to the requirements will result in improved presentation of information, which we expect to increase the usefulness of the disclosures for investors and generally lower the regulatory burden (and compliance costs) for registrants. In addition, we expect that improving the information environment with modernized and simplified disclosures for all filers will incrementally enhance capital formation and the allocative efficiency of the capital markets through more accurate share prices, better accountability of

<sup>305</sup> Relative to the random sample in Table 3 of the Proposing Release, the random sample in Table 3 of this release excludes definitive materials filed under the Securities Act Rule 497 because these materials do not include exhibits.

In counting the number of exhibits, we did not include the following exhibits: 101.INS XBRL Instance Taxonomy; 101.SCH XBRL Taxonomy Extension Schema Document; 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document; 101.DEF XBRL Taxonomy Extension Definition Linkbase Document; 101.LAB XBRL Taxonomy Extension Labels Linkbase Document; and 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document because XBRL exhibits are not covered by the amendments.

The random sampling did not result in any Forms N-5 and N-8B-2 being drawn.

<sup>306</sup> Based on a review of filings, the Commission observed in a recent rulemaking that approximately 39% of registrants qualified as smaller reporting companies. *See Smaller Reporting Company Definition*, Release No. 33-10513; 34-83550; File No. S7-12-16 (Sept. 10, 2018), available at <https://www.sec.gov/rules/final/2018/33-10513.pdf>. Literature provides evidence consistent with the idea that the costs of disclosure requirements can be higher for smaller than larger firms. *See, e.g.*, Engel, E., Hayes, R.M., & Wang, X., *The Sarbanes-Oxley Act and firms' going private decisions*. 44 J. of Acc. and Econ. 116, 116-145 (2007). Literature also provides some evidence that the benefits of disclosure requirements can be higher for smaller firms. *See, e.g.*, Eleswarapu, V.R., Thompson, R., & Venkataraman, K., *The Impact of Regulation Fair Disclosure: Trading Costs and Information Asymmetry*. 39 J. of Fin. and Quant. Anal. 209, 209-225 (2004).

managers, and increased capital market liquidity. We do not expect that the amendments will have a substantial effect on competition.

We expect some of the amendments to entail modest initial implementation costs. However, we believe that the initial costs will be manageable for most registrants. Furthermore, those costs will be offset by future savings as a result of simplified and streamlined disclosure requirements, after implementation. Some of the amendments, such as those that impose new data tagging, hyperlinking, or disclosure requirements, will involve not only implementation costs but will also increase compliance costs for registrants going forward, although as discussed below, we do not expect these additional costs to be significant relative to current compliance costs.

While the purpose of the proposed amendments is to simplify and modernize public company disclosure requirements without loss of material information, we acknowledge that the amendments could result in a loss of some information in certain cases, as discussed below. However, we believe the potential loss of information would be mitigated by the fact that registrants will continue to be required to provide material information, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.<sup>307</sup>

### C. Economic Analysis of the Specific Amendments: Amendments That Clarify, Streamline, or Update Existing Rules

#### 1. Amendments That Clarify or Streamline a Rule's Requirements

##### a. Description of Property (Item 102)

Item 102 requires disclosure of the location and general character of the principal plants, mines, and other materially important physical properties of the registrant and its subsidiaries. The staff has observed, however, that the item may elicit disclosure that is not material.<sup>308</sup> The amendments to Item 102 will clarify that a description of property is required only to the extent physical properties are material to the registrant and will make other clarifying amendments.<sup>309</sup> The amendments will

<sup>307</sup> See Rule 12b-20 [17 CFR 240.12b-20] and Rule 408(a) [17 CFR 230.408(a)].

<sup>308</sup> See FAST Act Report, *supra* note 7, at Recommendation B.1. See also Concept Release, *supra* note 9, at Section IV.A.6.b and SEC Staff's Report of the Task Force on Disclosure Simplification (Mar. 5, 1996) available at <https://www.sec.gov/news/studies/smpl.htm>.

<sup>309</sup> See *supra* Section II.B.1.

not modify the Item 102 requirements for companies in the mining, real estate, and oil and gas industries.

The main benefit of the amendments will be to reduce the amount of disclosure that is not material by emphasizing materiality and harmonizing the rule's thresholds for disclosure. The amendments also can facilitate compliance and avoid any confusion associated with different disclosure standards. The reduction in regulatory burden due to the amendments to Item 102 may extend to approximately 6,300 registrants.<sup>310</sup>

When Item 102 was originally adopted, registrants were more likely than they are today to maintain large physical properties and other assets, such as manufacturing plants.<sup>311</sup> For example, today's technology firms and finance firms tend to hold substantially less real estate than manufacturing firms held in the 1980s. The amendment to Item 102 accounts for this change in the nature of enterprise by clarifying that disclosure about a physical property need only be provided to the extent that it is material to the registrant. The risk of loss of information important for investment and voting decisions under the amendment is mitigated by the fact that Item 102 explicitly requires disclosure of material information and the fact that registrants may continue to disclose relevant property information elsewhere in their filings, such as in response to Item 101 (Description of Business).

##### b. Management's Discussion and Analysis of Financial Condition and Results of Operations (Item 303 and Item 5 of Form 20-F)

We are adopting a series of amendments to Item 303.<sup>312</sup> In this section, we discuss all amendments to Item 303 that are intended to clarify the rule's requirements, while in Section IV.D.1. below, we discuss amendments to the content of MD&A. Instruction 1 to Item 303(a) provides that, generally, MD&A shall cover the three-year period covered by the financial statements and either use year-to-year comparisons or any other formats that in the registrant's judgment would enhance a reader's

<sup>310</sup> We derive this number by taking the average number of registrants filing Forms 10-K between 2014 and 2018 as reported in Table 1 and excluding all companies in the mining, oil and natural gas, and real estate industries as of 2018. See *infra* Section VII.C.1.a. for a discussion of the estimated reduction in paperwork burden as a result of the amendments to Item 102.

<sup>311</sup> Since 1935, we have required disclosure similar to that required under Item 102. See Release No. 33-276 (Jan. 14, 1935) [not published in the **Federal Register**].

<sup>312</sup> See *supra* Section II.A.1.a.iii.

understanding. Additionally, the instruction states that reference to the five-year selected financial data may be necessary where trend information is relevant.

We are adopting as proposed the revision to Instruction 1 of Item 303 that eliminates the reference to year-to-year comparisons. Instruction 1 will now state that registrants may use any presentation that in the registrant's judgment enhances a reader's understanding of the registrant's financial condition, changes in financial condition, and results of operations, without suggesting that any one mode of presentation is preferable to another. We are also deleting the reference to five-year selected financial data in Instruction 1 to Item 303(a) as proposed.

These amendments emphasize the flexibility available to registrants with respect to the form of MD&A presentation. The major benefit of flexibility is that it allows registrants to frame the information in a way that emphasizes material information and allows registrants to omit information that is not material. One potential cost associated with this aspect of the amendment is that, to the extent the amendments lead to disclosure that varies more across firms and across a single firm's filings, they also may make disclosure less comparable across registrants and over time.

To maintain a consistent approach to MD&A for domestic registrants and foreign private issuers, we are adopting changes to Form 20-F similar to the changes to Item 303(a).<sup>313</sup> The disclosure requirements for Item 5 of Form 20-F are substantively comparable to the MD&A requirements under Item 303 of Regulation S-K. The economic effects of the amendments to Form 20-F are therefore similar to those for the amendments to Item 303(a) described above.

##### c. Risk Factors (Item 503(c))

Item 503(c) requires disclosure of the most significant factors that make an offering speculative or risky. We are relocating Item 503(c) from Subpart 500 to Subpart 100 of Regulation S-K.<sup>314</sup> We believe that Subpart 100 is a more appropriate location for the risk factor disclosure requirements because it covers a broad category of business information and is not limited to offering-related disclosure. Additionally, our amendments will eliminate the risk factor examples that

<sup>313</sup> See *supra* Section II.A.1.b.iii.

<sup>314</sup> See *supra* Section II.B.4.b.

are enumerated currently in Item 503(c).<sup>315</sup>

We do not expect that relocating the disclosure requirement within Regulation S–K will pose any additional costs to registrants or investors because we are only changing the location of the requirement in Regulation S–K. The content of the requirement will not change.

With respect to the elimination of the examples in Item 503(c), we believe that this may prompt registrants to more carefully evaluate and classify their risk exposures, which can ultimately benefit investors through more specific and relevant risk factor disclosures. In particular, the elimination of the examples in Item 503(c) can benefit investors because providing examples might anchor or skew the registrant's risk analysis in the direction of the examples.<sup>316</sup>

An alternative to the amendments, as suggested by some commenters, would be to expand or update the list of examples or revise them to specify generic risks that should not be disclosed. While such an approach might lead to incremental improvements in existing disclosures, it would not eliminate the anchoring effect discussed above nor would it serve to discourage generic or “boilerplate” disclosures as effectively as the amendments. It is also possible that a list of generic risks could inadvertently be viewed as exhaustive. In addition, specifying a list of generic risks that should not be disclosed may create a rule that needs to be regularly updated.

#### d. Plan of Distribution (Item 508)

Item 508 requires disclosure about the plan of distribution for securities in an offering, including information about underwriters. We are amending Rule 405 to define the term “sub-underwriter” to clarify its application in Item 508 of Regulation S–K.<sup>317</sup> We believe that defining the term “sub-underwriter” will reduce compliance costs by helping registrants to more easily determine what disclosure is required under Item 508. We also believe that a defined term can help investors better understand the role of “sub-underwriters” in the offering process. Because the amendment merely

clarifies an existing disclosure requirement, we believe any incremental costs would be nominal.<sup>318</sup>

#### e. Material Contracts (Item 601(b)(10))

Item 601(b)(10)(i) currently requires registrants to file every material contract not made in the ordinary course of business, provided that the contract meets one of two tests: (i) The contract must be performed in whole or in part at or after the filing of the registration statement or report, or (ii) the contract was entered into not more than two years before that filing. We are amending Item 601(b)(10)(i) to limit the two-year look back test to “newly reporting registrants,” as that term is defined in the proposed revision to Instruction 1 of Item 601(b)(10).<sup>319</sup>

We expect that the amendments will streamline reporting obligations while maintaining investor protection. Although the two-year look back test captures material contracts that were fully performed before the filing date, this test does not provide any new information to the market for registrants with established reporting histories. Excluding these registrants from the two-year look back requirement will marginally reduce their compliance burdens because they will not need to re-file (or incorporate by reference) agreements that were previously filed and are no longer in effect.<sup>320</sup> At the same time, investors will continue to have access to any material agreements that a registrant previously filed on EDGAR.

#### f. Amendments With a Minor or No Effect on Disclosure

The following amendments are expected to have minor impacts on the disclosure provided:

- Item 401—amendment will clarify what disclosure about executive officers does not need to be repeated in proxy or information statements if it is already included in Form 10–K.<sup>321</sup>
- Item 405—amendment will simplify the Section 16 reporting process by allowing registrants to rely on a review of Section 16 reports submitted on EDGAR instead of gathering reports furnished to the registrant.<sup>322</sup>

<sup>318</sup> See *infra* Section VII.C.3.a.

<sup>319</sup> See *supra* Section II.B.5.c.

<sup>320</sup> See *infra* Section VII.C.1.d.ii. for a discussion of the estimated reduction in paperwork burden as a result of the amendment to Item 601(b)(10)(i).

<sup>321</sup> See *supra* Section II.B.2.a. See also *infra* Section VII.C.1.c. for a discussion of the estimated reduction in paperwork burden as a result of the amendment to Item 401.

<sup>322</sup> See *supra* Section II.B.2.b. The amendment will also eliminate the requirement for reporting persons to furnish Section 16 reports to registrants, which could ease the compliance burden on

- Item 501(b)(1)—amendment will eliminate the portion of the item that discusses when a name change may be required and the exception to that requirement.<sup>323</sup>

- Item 501(b)(3)—amendment will allow registrants to move details of an offering price method or formula from the prospectus cover page to another location in the prospectus; the amendment also will require registrants to state that the price will be more fully explained in the prospectus and accompany that statement with a cross-reference to the more detailed offering price disclosure.<sup>324</sup>

- Item 501(b)(10)—amendment will streamline the prospectus legend requirements.<sup>325</sup>

- Incorporation by Reference—amendments will (i) provide clearer guidance on cross-referencing and (ii) consolidate the requirements for incorporation by reference in Securities Act Rule 411, Exchange Act Rule 12b–23, and related rules under the Investment Company Act and Investment Advisers Act to eliminate redundant or unnecessary requirements. With respect to cross-referencing or incorporating by reference to non-financial statement information from the financial statements, the amendments provide that incorporating by reference, or cross-referencing to, information outside of the financial statements is only permitted when permitted or required by the Commission's rules, U.S. GAAP, or IFRS.<sup>326</sup>

- Rule 312—amendment will not affect disclosure because the temporary accommodation that filers can post static pool disclosures on an internet website in lieu of filing the information on EDGAR lapsed in June 30, 2012. The amendment also will not affect recordkeeping costs because the requirement to retain all versions of the information provided through the website lapsed in June 30, 2017.<sup>327</sup>

We believe that the above amendments, which will alter existing

reporting persons. See *infra* Section VII.C.1.c. for a discussion of the estimated reduction in paperwork burden as a result of the amendment to Item 405.

<sup>323</sup> See *supra* Section II.B.4.a.i. The amendment to Item 501(b)(1) is not expected to meaningfully affect paperwork burdens. See *infra* Section VII.C.3.a.

<sup>324</sup> See *supra* Section II.B.4.a.ii. The amendment to Item 501(b)(3) is not expected to meaningfully affect paperwork burdens. See *infra* Section VII.C.3.a.

<sup>325</sup> See *supra* Section II.B.4.a.iv. The amendment to Item 501(b)(10) is not expected to meaningfully affect paperwork burdens. See *infra* Section VII.C.3.a.

<sup>326</sup> See *supra* Sections II.A.3.c. and II.B.6. The amendments governing incorporation by reference are not expected to meaningfully affect paperwork burdens. See *infra* Section VII.C.3.b.

<sup>327</sup> See *supra* Section II.D.

<sup>315</sup> See *id.*

<sup>316</sup> There is extensive evidence in psychology and economics that individuals tend to rely too heavily on the first piece of information offered (the “anchor”) when making decisions. See, e.g., Tversky, A. & Kahneman, D., *Judgment under Uncertainty: Heuristics and Biases*. 185 Science 1124. 1124–1131 (1974).

<sup>317</sup> See *supra* Section II.B.4.c.

disclosure practices only to a minor degree, will allow registrants to improve the readability and navigability of disclosure documents and reduce repetition. Because the amendments do not significantly change the required disclosures and continue to elicit all material information, we do not envision any significant incremental costs associated as a result of the amendments.

An alternative amendment that we considered was to allow registrants to exclude item numbers and captions or to create their own captions tailored to their disclosure in Form 10, Form 10-K, and Form 20-F. The benefit of such an amendment would be that it potentially would reduce repetitive disclosure or unnecessary cross-references when information may be responsive to more than one item and thereby enhance the overall readability of required disclosures. Nevertheless, as noted by commenters, this amendment potentially would hamper the ability of investors to navigate filings, locate information important to them, and compare information across registrants.

Another alternative that we considered was to require registrants to include in the exhibit of all of their subsidiaries the LEI, if one has been obtained, of the registrant and each subsidiary listed, and require the LEIs to be tagged using Inline XBRL. The benefits of such an amendment would be that it potentially would allow investors to use LEIs to more quickly and precisely identify registrants and their subsidiaries, and thus better understand relationships between interrelated companies and the associated risks.<sup>328</sup> Nevertheless, as noted by some commenters, it would be costly and time consuming to acquire and maintain LEIs, particularly for registrants with numerous subsidiaries or affiliates operating globally, while at the same time LEIs may not provide additional material information to investors.<sup>329</sup>

## 2. Amendments To Update Rules to Account for Subsequent Developments

The following amendments will update existing rules to account for subsequent developments and are expected to have minor impacts on the disclosure provided:

- Item 407(d)—amendment will update the outdated reference to AU sec. 380 in Item 407(d)(3)(i)(B).<sup>330</sup>

<sup>328</sup> See *supra* notes 282 and 283.

<sup>329</sup> See *supra* notes 284 and 285.

<sup>330</sup> See *supra* Section II.B.3.a. See also *infra* Section VII.C.1.c. for a discussion of the estimated reduction in paperwork burden as a result of the amendment to Item 407(d).

- Item 407(e)—amendment will update requirements for compensation committee disclosure to exclude EGCs because they are not required to include a CD&A.<sup>331</sup>

- Item 512—amendment will eliminate certain undertakings that are redundant and obsolete.<sup>332</sup>

We believe that the amendments listed above will reduce potential confusion in applying our rules, result in more consistent disclosure practices, and ease compliance burdens for registrants, with a minimal impact on the information available to investors. We do not envision any significant incremental costs associated with the amendments because the substance of the rules will not change.

### *D. Economic Analysis of the Specific Amendments: Amendments That Simplify the Disclosure Process or Eliminate Disclosures*

#### 1. Management's Discussion and Analysis (Item 303 and Item 5 of Form 20-F)

We are revising Instruction 1 to Item 303(a) and Item 5 of Form 20-F to allow registrants who are providing financial statements covering three years in a filing to omit discussion of the earliest of the three years if such discussion was already included in any other of the registrant's prior filings on EDGAR that required disclosure in compliance with Item 303 of Regulation S-K or Item 5 of Form 20-F; provided, that registrants electing not to include a discussion of the earliest year in reliance on this instruction identify the location in the prior filing where the omitted discussion may be found.<sup>333</sup>

We believe that the main economic benefit of the amendments to Item 303 and Item 5 of Form 20-F will be to simplify and modernize MD&A while still providing all material information. This is intended to facilitate a better understanding of the firm's financial prospects. Because MD&A is typically one of the most labor-intensive pieces of disclosure to produce, eliminating the requirement to discuss the earliest year financial statements in some circumstances can meaningfully reduce compliance costs for registrants.<sup>334</sup>

<sup>331</sup> See *supra* Section II.B.3.b. See also *infra* Section VII.C.1.c for a discussion of the estimated reduction in paperwork burden as a result of the amendment to Item 407(e).

<sup>332</sup> See *supra* Section II.B.4.d. The amendment to Item 512 is not expected to meaningfully affect paperwork burdens. See *infra* Section VII.C.3.a.

<sup>333</sup> See *supra* Section II.A.1.a.iii.

<sup>334</sup> See *infra* Section VII.C.1.b for a discussion of the estimated reduction in paperwork burden as a result of the amendments to Item 303(a) and Item 5 of Form 20-F.

One potential cost of the amendments is that investors may receive less information about earlier period financial results within a filing. Although previously disclosed information can provide helpful context for the new information being disclosed, this information would have been incorporated into market prices of publicly traded firms when it was originally presented. In addition, registrants electing not to include a discussion of the earliest year in reliance on this instruction will be required to identify the location in the prior filing where the omitted discussion may be found, which will mitigate the omission of the discussion in the filing at issue.

#### 2. Information Omitted From Exhibits

Item 601(a)(5), as amended, will permit registrants to omit schedules and attachments to all exhibits under Item 601 unless they contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document.<sup>335</sup> The amendments also will require registrants to provide with each exhibit a list briefly identifying the contents of all omitted schedules and attachments. In addition, registrants will be required to provide, on a supplemental basis, a copy of any of the omitted schedules or attachments to the Commission staff upon request. We are also adding comparable provisions to the exhibit requirements of Item 1016 of Regulation M-A, the investment company registration forms, and Form N-CSR.

Allowing registrants to omit schedules and attachments that are not material to all exhibits should lower their filing costs. The omission of schedules that are not material will also help investors more clearly focus on the material disclosures.

We are unable to estimate the number of schedules and attachments that will be omitted as a result of the amendments of Item 601(a)(5), Item 1016 of Regulation M-A, and the investment company registration forms because we cannot determine whether a schedule and attachment contains material information without additional information from registrants.<sup>336</sup> Nevertheless, we believe that the

<sup>335</sup> See *supra* Section II.B.5.b.i.

<sup>336</sup> See *infra* Section VII.C.1.d.i.2 for a discussion of the reduction in paperwork burden as a result of the amendments to Item 601(a)(5), Item 1016 of Regulation M-A, and the investment company registration forms. While there will be some reduction in burden associated with these amendments, we do not believe the reduction will be significant enough to warrant an adjustment to our burden estimates.

number of schedules and attachments that will be omitted as a result of the amendments likely will be small. The reason is that Item 601(a)(5), Item 1016 of Regulation M–A, and the investment company registration forms only permit schedules and attachments that contain no material information to be omitted, and we believe that the majority of the schedules and attachments contain at least some material information and thus cannot be omitted. Consequently, while there will be some reductions in filing costs associated with the amendments, any such reductions likely will be small.

Item 601(a)(6), as amended, will permit registrants to omit PII without submitting a confidential treatment request under Rule 406 or Rule 24b–2.<sup>337</sup> Under the amendment, registrants also will not be required to provide an analysis in order to redact PII from exhibits. We are also adding comparable provisions to the exhibit requirements of Item 1016 of Regulation M–A and the investment company registration forms. Since the amendments leave the decision about omission of PII entirely to the registrant, it could result in more liberal redactions. Thus, there is a tradeoff between reduced compliance costs and the potentially adverse effects of reduced disclosure. However, our analysis indicates that the Commission received very few confidential treatment requests in reliance on the FOIA exemption concerning PII. As an illustration, in fiscal year 2018, the Commission received 14 confidential treatment requests pursuant to this FOIA exemption, out of which 10 were granted. Presumably, most registrants are currently taking advantage of the existing staff position that PII may be omitted without filing a confidential treatment request. As a result, we do not expect that codifying this accommodation will significantly alter existing disclosure practices or will significantly reduce the costs associated with preparing analysis and confidential treatment requests to omit PII.<sup>338</sup>

We are also amending 601(b)(10) and (2) and certain related requirements in specified disclosure forms for which Item 601(b)(10) does not apply to permit registrants to omit confidential information in material contract exhibits that is both (i) not material and (ii) would likely cause competitive harm to

the registrant if publicly disclosed, without submitting a confidential treatment request.<sup>339</sup> The disclosure forms for which Item 601(b)(10) does not apply and that will be affected by the amendment are Forms 20–F, 8–K, N–1A, N–2, N–3, N–4, N–5, N–6, N–8B–2, N–14, and S–6. Instead of requesting confidential treatment, registrants will be required to mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of each redacted exhibit that certain information is omitted from the filed version of the exhibit. The registrant will also be required to indicate with brackets where the information is omitted from the filed version of the exhibit.

Registrants can be asked by the Commission staff to provide on a supplemental basis an unredacted copy of the exhibit. The staff also can request that the registrant provide an analysis of why the redacted information is both (i) not material and (ii) would likely cause it competitive harm if publicly disclosed. Registrants may request confidential treatment of this supplemental information pursuant to Rule 83 while it is in the possession of the staff.

The amendment will significantly reduce the costs associated with preparing confidential treatment requests and expedite the filing process.<sup>340</sup> The largest cost associated with the confidential treatment request process is the cost to prepare the letter and application for the request, which can require substantial legal analysis. The amendment of Items 601(b)(10) and (2) will eliminate the costs associated with preparing confidential treatment requests, except for cases when Commission staff asks the registrant to provide an analysis of why the redacted information is immaterial and would likely cause the registrant competitive harm if publicly disclosed.

In this regard, one commenter on the Concept Release reviewed seven different confidential treatment requests on which it assisted clients since 2012 and found that legal fees alone ranged from approximately \$35,000 to over \$200,000.<sup>341</sup> A commenter on the Proposing Release mentioned that “[d]uring [its] 2017 fiscal year, [it] submitted 39 confidential treatment requests, and [it] submitted a total of 17 confidential treatment requests during

the first two quarters of [its] 2018 fiscal year. Attorneys and paralegals at [the] company spend an average of 80 hours each quarter preparing redacted exhibits and related confidential treatment requests.”<sup>342</sup> According to another commenter, any cost savings likely will be more pronounced for smaller companies “because smaller reporting companies have a lower threshold for determining whether a contract is material and therefore required to be filed publicly in the first place” and for companies in certain industries that require confidential treatment more frequently (e.g., biotechnology).<sup>343</sup>

Because more than 90% of the confidential treatment requests granted by the Commission in fiscal year 2018 were made in reliance on the FOIA exemption concerning competitive harm, the amendments to allow registrants to omit competitively harmful information that is not material without filing a confidential treatment request could correspondingly reduce the number and cost of confidential treatment requests pursuant to Rule 406 and Rule 24b–2 by over 90%. This cost reduction will be mitigated by the fact that registrants will continue to incur costs associated with preparing the redacted exhibits for filing and negotiating with counterparties over what terms of the agreement can be publicly disclosed. In addition, this cost reduction partially will be offset by the amendment’s provision that the staff may request an analysis similar to the current competitive harm analysis. Registrants will incur costs to prepare and provide this analysis in response to any request from the staff.

One potential cost of the amendments is that information may be redacted that would not otherwise be afforded confidential treatment by the staff. However, based on previous experience and a review of confidential treatment requests, we believe that such instances will be rare. Over the past two fiscal years, about 11% of the confidential treatment requests granted by the Commission were revised by the registrant in response to staff comments

<sup>342</sup> The 80-hour burden estimate provided by the commenter includes both time spent to prepare redacted exhibits and time spent to prepare confidential treatment requests. Under the amendments to Items 601(b)(10) and (2), registrants will continue to spend time preparing redacted exhibits to file with the Commission, regardless of whether they will submit a confidential treatment request for those exhibits. Hence the 80-hour burden estimate likely overstates any cost savings associated with removing the need to submit a confidential treatment request under the amendments to Items 601(b)(10) and (2). See letter from FedEx Corporation.

<sup>343</sup> See letter from Reed Smith.

<sup>337</sup> See *supra* Section II.B.5.b.ii.

<sup>338</sup> See *infra* Section VII.C.1.d.i.3 for a discussion of the reduction in paperwork burden as a result of the amendments related to PII. We believe that the amendments will result in some incremental reduction in burden, although we do not believe the reduction will be significant enough to warrant an additional adjustment to our burden estimates.

<sup>339</sup> See *supra* Section II.A.2.c.

<sup>340</sup> See *infra* Section VII.C.1.d.i.1 for a discussion of the estimated reduction in paperwork burden as a result of the amendments related to confidential information in material contracts.

<sup>341</sup> See letter from Fenwick.

to reduce and/or modify the requested redactions. In addition, over the past five fiscal years, very few confidential treatment requests were denied by the staff. Specifically, of the confidential treatment requests filed over the last five fiscal years, on average, approximately 1% were withdrawn because the staff determined that the information likely was material to investors.<sup>344</sup> During this time, on average, approximately 95% of confidential treatment requests filed were granted, and requests were rarely denied.<sup>345</sup> Also during the past five fiscal years, on average, approximately 11% of confidential treatment requests filed were revised prior to the request being granted to limit the number of terms redacted based on likely materiality or overly broad redactions.<sup>346</sup> Under the amendments, the Commission staff will continue its selective review of registrant filings and will selectively assess whether redactions from exhibits appear to be limited to information that is not material and that would likely cause the registrant competitive harm if publicly disclosed. This selective review process will mitigate the risk that material information may be redacted from Commission filings as a result of the proposed amendments.

#### *E. Economic Analysis of the Specific Amendments: Amendments That Require More Disclosure or the Incorporation of New Technology*

##### 1. Description of Registrant's Securities (Item 601(b)(4))

Item 202 requires registrants to provide a brief description of their

<sup>344</sup> The following confidential treatment requests were received and withdrawn for likely materiality during the last five fiscal years:

2018: 1,239 received and approximately 2 withdrawn;

2017: 1,226 received and approximately 4 withdrawn;

2016: 1,271 received and approximately 7 withdrawn;

2015: 1,369 received and approximately 14 withdrawn; and

2014: 1,413 received and approximately 19 withdrawn.

<sup>345</sup> In fiscal years 2018, 2017, 2016, and 2015, no CTRs were denied. In fiscal year 2014, one CTR was denied. On average, during the last five fiscal years, approximately 95% of confidential treatment requests were granted and approximately 5% were withdrawn. In addition to withdrawals based on staff determinations that the information was likely material, other reasons confidential treatment requests are withdrawn include that the offering is no longer going forward, the information is already public, or the contract is no longer material.

<sup>346</sup> Confidential treatment requests revised based on materiality and/or overbroad redactions in fiscal years 2018, 2017, 2016, 2015, and 2014 were approximately 133, 137, 119, 139, and 183, respectively.

registered capital stock, debt securities, warrants, rights, American Depositary Receipts, and other securities. We are amending Item 601(b)(4) to require registrants to provide Item 202 disclosure as an exhibit to Form 10-K for each class of securities that is registered under the Exchange Act, rather than limiting this disclosure to registration statements.<sup>347</sup> The amendments will not change existing disclosure obligations under Form 8-K and Schedule 14A, which currently require registrants to disclose certain modifications to the rights of their security holders and amendments to their articles of incorporation or bylaws. Any modifications and amendments during a fiscal year to the information called for by Item 202 will now also be reflected in an exhibit to the registrant's next annual report.

Information about Exchange Act registered securities allows investors to assess the existing capital structure of registrants, which can help investors better understand their exposure to risks and their control rights. Currently, this information is not always easy to locate because it requires cross-referencing to the date of the original offering of each type of security, and in the cases of companies that have not issued new securities since Item 202 came into effect, this information may not be available.<sup>348</sup> Requiring Item 202 disclosure as an exhibit to annual reports will improve investors' access to information about their rights as security holders, thereby facilitating more informed investment and voting decisions. This requirement also will level the playing field across registrants because the same type of information will be available for all registrants' securities.<sup>349</sup>

The requirements will impose some incremental compliance costs for registrants to include the additional disclosure with their annual reports.<sup>350</sup> Table 1 above shows that on average approximately 7,600 registrants file Form 10-K each year and therefore will be subject to the new Item 601(b)(4) exhibit filing requirement. However, because registrants already prepare very similar disclosure to satisfy existing disclosure obligations under Form 8-K and Schedule 14A and will be able to incorporate by reference and hyperlink to prior disclosure, so long as there has not been any change to the information

<sup>347</sup> See *supra* Section II.B.5.a.

<sup>348</sup> See letter from SIFMA.

<sup>349</sup> See *id.*

<sup>350</sup> See *infra* Section VII.C.2.b. for a discussion of the estimated increase in paperwork burden as a result of the amendment to Item 601(b)(4).

called for by Item 202, we expect these incremental costs to be minimal.<sup>351</sup>

##### 2. Tagging Cover Page Data

We are requiring registrants to tag all of the information on the cover page of Form 10-K, Form 10-Q, Form 8-K, Form 20-F, and Form 40-F using Inline XBRL.<sup>352</sup> To implement the cover page tagging requirements, we are adding new Rule 406 to Regulation S-T, new Item 601(b)(104) to Regulation S-K, new paragraph 104 to the "Instructions as to Exhibits" of Form 20-F and new paragraph B.17 to the "General Instructions" of Form 40-F to require registrants to file with each of the specified forms a "Cover Page Interactive Data File" containing cover page data. We are also revising Rule 11 of Regulation S-T to add the term "Cover Page Interactive Data File." In addition, we are amending the cover pages of these forms to include the trading symbol for each class of the registrant's registered securities.<sup>353</sup>

Investment analysis increasingly relies on quantitative statistical methods. Machine-readable formats greatly facilitate quantitative analysis because they allow for the corresponding items to be imported directly into various platforms for data analysis. Thus, tagging all the data

<sup>351</sup> One commenter suggested that without the option to incorporate by reference "preparation of new exhibits by a registrant with multiple classes of registered debt securities would substantially exceed the 0.5 hours of paperwork burden estimated on page 158 of the proposing release, since exhibit preparation would require making conforming edits to the 'Description of Notes' for each class of security and might also involve combining disclosure from a base prospectus and prospectus supplement into one narrative. We also anticipate that a registrant would request outside transaction counsel to review the exhibit, increasing the cost and preparation time." See letter from Davis Polk. Another commented, however, argued that "[a]lthough there will be an initial burden (in drafting new disclosure or expanding old/existing disclosure) for issuers with securities that caused them to become subject to Section 12 before Item 202 came into effect, in those cases this burden will be a one-time event, and in all other cases registrants will only need to copy the Item 202 from the offering of each Section 12 registered security to the Item 202 annual report exhibit." See letter from SIFMA.

<sup>352</sup> See *supra* Section II.B.7.a.

<sup>353</sup> Because the cover pages of Form 10-K, Form 20-F, and Form 40-F already require disclosure of the title of each class of securities registered pursuant to Section 12(b) of the Exchange Act and each exchange on which they are registered, the amendments to these forms revise the cover page to include a corresponding field for the trading symbol. Unlike these forms, however, the cover pages of Form 10-Q and Form 8-K do not currently require disclosure of the title of each class of securities and each exchange on which they are registered. Accordingly, to ensure that registrants and their registered securities are identified in a consistent manner across forms, we are revising the cover pages of Form 10-Q and Form 8-K to include this disclosure in addition to the trading symbol.

points on the cover pages of Form 10-K, Form 10-Q, Form 8-K, Form 20-F, and Form 40-F can decrease the costs to investors for implementing quantitative data analysis. In addition, relevant information will be available more quickly, at a more granular level, with greater accuracy, and with greater efficiency.<sup>354</sup> We acknowledge that the amendment will impose additional costs on registrants but expect the additional burden to be small, given that registrants already furnish a substantial amount of information contained in these forms in a structured format.<sup>355</sup> The amendments will also facilitate future enhancements to the EDGAR system by utilizing the tagged information to reduce duplicative entry of information into both the filing and the submission header at the time of filing. One commenter stated that it would take 1–2 hours to complete tagging for a cover page, that tagging the cover page a second time would require less time, and that filers would be able to use their current XBRL tagging processes to perform the cover page tagging.<sup>356</sup> The same commenter indicated that the biggest challenge with the tagging requirements is that the legal department may be required to prepare certain filings whereas the finance department is responsible for preparing other filings, but that this issue will only affect certain companies.

An alternative to the Inline XBRL or traditional XBRL format is to specify an XML format for the cover pages of Form 8-K, Form 10-K, Form 10-Q, Form 20-F, and Form 40-F. An XML format could have a variety of implementations ranging from filers submitting the data according to a designated technical framework to inputting the cover page information in a web-fillable format within EDGAR. We are not adopting this approach because the Inline XBRL format provides precise rules that facilitate consistent input and data validation by filers and enhance the analytical capabilities of data users. Moreover, the Inline XBRL and traditional XBRL format have more

<sup>354</sup> See letter from XBRL US and Morningstar. See XBRL Adopting Release, *supra* note 255, for a discussion of the benefits of data tagging. See also *Inline XBRL Filing of Tagged Data*, Release No. 33–10323 (Mar. 1, 2017) [82 FR 14282 (Mar. 17, 2017)], at n. 169 and *Inline XBRL Adopting Release*, *supra* note 258, at n. 71 for a discussion of academic research on the benefits of XBRL.

Some commenters questioned the extent to which the cost of data tagging for registrants outweighs the potential value to investors. See letters from CCMC, Financial Executives International, IMA, Nasdaq, Society for Corp. Gov., and UnitedHealth.

<sup>355</sup> See *infra* Section VII.C.2.c. for a discussion of the estimated increase in paperwork burden as a result of the requirement to tag cover page data.

<sup>356</sup> See letter from XBRL US.

robust data validation capabilities, which will help to ensure better data quality for investors. Inline XBRL also does not suffer from possible data quality discrepancies that may occur from filers rekeying the information from their cover page for submission in XBRL or XML.<sup>357</sup>

### 3. Amendments for Additional Disclosure With Minimal Additional Costs to Registrants

The following amendments are expected to impose only limited compliance costs on registrants:

- Incorporation by Reference—amendment will require hyperlinks internal to EDGAR for documents incorporated by reference.<sup>358</sup>
- Item 501(b)(4)—amendment will require disclosure on the prospectus cover page of any national securities exchange where the securities being offered are listed or, if not listed, the principal United States market or markets for the securities being offered and the corresponding trading symbols, if any.<sup>359</sup>

Requiring registrants to include hyperlinks to information that is incorporated by reference can improve the readability and navigability of disclosure documents by allowing users to be taken directly to the incorporated information by clicking on a link rather than having to locate the information on EDGAR. Although requiring the inclusion of hyperlinks and the updating of inaccurate hyperlinks for incorporated information will impose an additional compliance burden on registrants,<sup>360</sup> we do not expect this burden to be significant given that hyperlinks are relatively easy to implement and involve minimal cost and because Commission rules already require registrants to be familiar with hyperlinking.<sup>361</sup>

In the case of Item 501(b)(4), expanding the existing requirements for

<sup>357</sup> Registrants that use Inline XBRL would incur costs to switch to a newer technology, if such technology became available. Nevertheless, based on our experience with the Inline XBRL voluntary filing program—when filers switched from XBRL to Inline XBRL—we believe any such switching costs likely would be minimal. See *Inline XBRL Adopting Release*, *supra* note 258.

<sup>358</sup> See *supra* Section II.B.6.b.ii. See *infra* Section VII.C.3.b. for a discussion of the effect on paperwork burdens as a result of this amendment.

<sup>359</sup> See *supra* Section II.B.4.a.iii. See *infra* Section VII.C.2.a. for a discussion of the estimated increase in paperwork burden as a result of the amendments to Item 501(b)(4).

<sup>360</sup> See *infra* Section II.B.6.b.ii for a discussion of hyperlinking requirements and the requirements to file an amendment to a document to correct an inaccurate hyperlink.

<sup>361</sup> See Exhibit Hyperlinks Adopting Release, *supra* note 10.

trading market disclosure to encompass information about markets that are not “national securities exchanges” will benefit investors by helping them to better assess their trading costs. The disclosure will impose some additional disclosure costs on registrants. However, we do not expect these costs to be significant given that registrants should have ready access to this information. In this regard, we note that the required disclosure will be limited to the principal United States market or markets where the registrant, through the engagement of a registered broker-dealer, has actively sought and achieved quotation.

### F. Economic Analysis of HTML and Hyperlinking Requirements of Forms Under the Investment Company Act

As discussed above, we are adopting HTML and hyperlinks requirements for filers of certain forms under the Investment Company Act.<sup>362</sup> Broadly speaking, we believe the amendments will reduce search costs for investors. In particular, we believe that exhibit hyperlinks will help investors and other users to access a particular exhibit more efficiently as they will not need to search within the filing or through different filings made over time to locate the exhibit. Requiring exhibit hyperlinks may make it easier for investors and other users to find and access a particular exhibit that was originally filed with a previous filing.

To the extent that hyperlinks ease the navigation process for investors and other users, hyperlinks may also facilitate a more thorough review of a registrant’s registration statements, applications, and reports and encourage more effective monitoring over time. The potential reduction of search costs and the enhanced ability of investors to review a registrant’s disclosure may result in more informed investment and voting decisions, potentially enhancing allocative efficiency, and capital formation by registrants.

We expect that hyperlinks will be more beneficial in reducing search costs in the case of exhibits incorporated by reference than in the case of exhibits filed with the filing. In particular, we expect these benefits to be most pronounced in the case of incorporation by reference from a filing that was not recently filed because more recent filings are displayed first on the EDGAR search results page. Further, we expect hyperlinks will have greater benefits in the case of registrants that submit more filings.

<sup>362</sup> See *supra* Sections II.B.6.b.ii and II.B.7.b.

As a result of the amendments, we expect that both HTML and ASCII registrants will incur compliance costs to include hyperlinks in their exhibit indexes. While the average cost itself of inserting a hyperlink is minimal, the total hyperlinking costs for registrants will be a function of two main factors: (1) How many registration statements, applications and reports a registrant files that require an exhibit index; and (2) the number of exhibits filed or incorporated by reference in the filing.<sup>363</sup>

Filers reporting in ASCII will incur costs to switch to HTML, in addition to the costs of including hyperlinks in their exhibit indexes. As Table 2 above shows, during calendar year 2018, approximately 10% of the filings that will be affected by the amendments were filed in ASCII. The limited use of ASCII indicates that the final amendments will affect only a limited number of registrants on a one-time basis. While the registrants that file forms in ASCII that will be affected by the amendment to require HTML are primarily small entities, we expect that the costs of switching to HTML will not be significant because the cost of software with built-in HTML and hyperlink features is minimal. In addition, the costs associated with the HTML and hyperlinking requirements will be mitigated by the adoption of a transition period that is intended to provide investment company registrants time to prepare filings to include hyperlinks and mitigate the cost burdens related to switching over to HTML format.<sup>364</sup>

Overall, given the modest costs involved, we do not expect that the amendments will have significant competitive effects for registrants.

## VII. Paperwork Reduction Act

### A. Background

Certain provisions of our rules and forms that would be affected by the amendments contain “collection of information” requirements within the meaning of the Paperwork Reduction Act of 1995 (“PRA”).<sup>365</sup> We published a notice requesting comment on changes to these collection of information requirements in the Proposing Release and have submitted these requirements to the Office of Management and Budget (“OMB”) for review in accordance with

the PRA.<sup>366</sup> The hours and costs associated with preparing and filing the forms and reports constitute reporting and cost burdens imposed by each collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid OMB control number. Compliance with the information collections is mandatory. Responses to the information collections are not kept confidential and there is no mandatory retention period for the information disclosed. The titles for the collections of information are:

“Regulation S–K” (OMB Control No. 3235–0071);<sup>367</sup>

“Regulation S–T” (OMB Control No. 3235–0424);

“Regulation 12B” (OMB Control No. 3235–0062);

“Regulation C” (OMB Control No. 3235–0074);

“Family of rules under section 8(b) of the Investment Company Act of 1940” (OMB Control No. 3235–0176);

“Form S–1” (OMB Control No. 3235–0065);

“Form S–3” (OMB Control No. 3235–0073);

“Form S–4” (OMB Control No. 3235–0324);

“Form S–6” (OMB Control No. 3235–0184);

“Form S–11” (OMB Control No. 3235–0067);

“Form N–14” (OMB Control No. 3235–0336);

“Form F–1” (OMB Control No. 3235–0258);

“Form F–3” (OMB Control No. 3235–0256);

“Form F–4” (OMB Control No. 3235–0325);

“Form F–7” (OMB Control No. 3235–0325);

“Form F–8” (OMB Control No. 3235–0378);

“Form F–80” (OMB Control No. 3235–0404);

“Form F–10” (OMB Control No. 3235–0380);

“Form SF–1” (OMB Control No. 3235–0707);

“Form SF–3” (OMB Control No. 3235–0690);

“Form 10” (OMB Control No. 3235–0064);

“Form 20–F” (OMB Control No. 3235–0288);

“Form 40–F” (OMB Control No. 3235–0381);

“Form 10–K” (OMB Control No. 3235–0063);

“Form 10–Q” (OMB Control No. 3235–0070);

“Form 8–A” (OMB Control No. 3235–0056);

“Form 8–K” (OMB Control No. 3235–0060);

“Form 10–D” (OMB Control No. 3235–0604);

“Schedule 14A” (OMB Control No. 3235–0059);

“Schedule 14C” (OMB Control No. 3235–0057);

“Form N–1A” (OMB Control No. 3235–0307);

“Form N–2” (OMB Control No. 3235–0026);

“Form N–3” (OMB Control No. 3235–0316);

“Form N–4” (OMB Control No. 3235–0318);

“Form N–5” (OMB Control No. 3235–0169);

“Form N–6” (OMB Control No. 3235–0503);

“Form N–8B–2” (OMB Control No. 3235–0186); and

“Form N–CSR” (OMB Control No. 3235–0570).

The forms, reports, and regulations listed above were adopted under the Securities Act, the Exchange Act, and/or the Investment Company Act. The regulations, schedules, and forms set forth the disclosure requirements for registration statements, periodic and current reports, distribution reports and proxy and information statements filed by registrants to help investors make informed investment and voting decisions. Other forms and reports are filed by entities regulated by the Investment Company Act in connection with the Commission’s oversight of these entities.

As described in more detail above, we are adopting amendments to modernize and simplify certain disclosure requirements in Regulation S–K and related rules and forms in a manner that reduces the costs and burdens on registrants while continuing to provide all material information to investors. The amendments are also intended to improve the readability and navigability of the Commission’s disclosure documents and discourage repetition and disclosure of immaterial information. In addition, we are adopting parallel amendments to several rules and forms applicable to investment companies and investment advisers to provide for a consistent set of incorporation by reference and hyperlinking rules for these entities, including amendments that will require

<sup>363</sup> See *infra* Section VII.C.2.c. for a discussion of the estimated increase in paperwork burden as a result of the requirements related to HTML and hyperlinks.

<sup>364</sup> See *supra* Section V.

<sup>365</sup> 44 U.S.C. 3501 *et seq.*

<sup>366</sup> 44 U.S.C. 3507(d) and 5 CFR 1320.11.

<sup>367</sup> The paperwork burdens for Regulation S–K, Regulation S–T, Regulation C and Regulation 12B are imposed through the forms that are subject to the requirements in these regulations and are reflected in the analysis of those forms. To avoid a PRA inventory reflecting duplicative burdens and for administrative convenience, we assign a one-hour burden to each of these regulations.

certain investment company filings to be submitted in HTML format.

### B. Summary of Comment Letters and Revisions to PRA Estimates

In the Proposing Release, the Commission requested comment on the PRA burden hour and cost estimates and the analysis used to derive such estimates. We did not receive any comments that directly addressed the PRA analysis of the proposed amendments.<sup>368</sup>

As discussed, we have made some changes to the proposed amendments as a result of comments received, but we do not expect any of those changes to meaningfully impact our assessment of the compliance burdens for purposes of the PRA. Accordingly, we have not revised the estimates from the Proposing Release of each amendment's impact on the per hour burden for each affected form. However, we have modified the overall burden estimates for each form to reflect the most current collections of information data from OMB and updated data on confidential treatment requests for the Commission's most recently completed fiscal year.

### C. Summary of the Amendments' Impact on Collections of Information

In this section, we summarize the amendments and their general impact on the paperwork burden associated with the forms listed above in Section V.A. In Section V.D. below, we provide revised burden estimates for each form.

#### 1. Amendments Expected To Decrease Burdens

##### a. Description of Property (Item 102)

The amendments to Item 102 of Regulation S-K make clarifying changes to the disclosure requirements of that item, including specifying that a description of property is only required to the extent physical properties are material to the registrant.<sup>369</sup> The staff has observed that the current disclosure standard may lead registrants, in some instances, to devote resources to providing disclosure about properties that are not material. Although the amendments to Item 102 are expected to help registrants avoid unnecessary disclosure, the amendments clarify, but do not reduce, existing requirements and therefore we do not believe they would significantly affect the paperwork burden associated with affected forms.

<sup>368</sup> One commenter referenced the estimated increase of 0.5 hours to the paperwork burden associated with Form 10-K and Form 20-F expected to result from new Item 601(b)(4)(iv), but did not comment on the underlying analysis. See letter from Davis Polk.

<sup>369</sup> See *supra* Section II.B.1.

Accordingly, we estimate that the paperwork burden will be reduced by 0.5 hours for each form affected by the amendments. We expect that Form S-1, Form S-4, Form 10, and Form 10-K will be affected by this amendment.

##### b. Management's Discussion and Analysis (Item 303 of S-K and Item 5 of Form 20-F)

The amendments to Item 303 and Item 5 of Form 20-F allow registrants, in some circumstances, to omit discussion of the earliest year from the MD&A.<sup>370</sup> The amendments also eliminate the reference to five-year selected financial data in Instruction 1 to Item 303(a) and clarify that registrants may use their discretion in selecting the best format for their MD&A presentation.<sup>371</sup> The combined effects of these amendments will be to eliminate the burden on registrants to prepare and provide repetitive disclosure that is not material. The amendments are of particular significance because MD&A is typically one of the most labor-intensive sections of any form in which it is required. We anticipate that the amendments to simplify and clarify the MD&A requirements will reduce the paperwork burden associated with affected forms.

We estimate that the aggregate impact of the amendments will be a four hour reduction in paperwork burden each time Item 303 information is required to be included in a form. We estimate that the aggregate impact of the corresponding amendments to Form 20-F will result in a four hour reduction each time information under Item 5 of that form is required. We expect that Form S-1, Form S-4, Form S-11, Form F-1, Form F-4, Form 10, Form 10-K, Form 10-Q, and Form 20-F will be affected by this amendment.

##### c. Directors, Executive Officers, Promoters and Control Persons (Item 401, Item 405 and Item 407)

The amendments to Item 401, Item 405, and Item 407 of Regulation S-K simplify and modernize our executive officer, Section 16(a) compliance and corporate governance disclosure requirements. The amendments to Item 401 simplify the rules for determining what disclosure about executive officers may be included in Form 10-K when other disclosure in Part III of Form 10-K will be incorporated by reference to the registrant's definitive proxy or information statement.<sup>372</sup> The amendments to Item 405 allow

<sup>370</sup> See *supra* Section II.A.1.

<sup>371</sup> See *id.*

<sup>372</sup> See *supra* Section II.B.2(a).

registrants to rely on a review of Section 16 reports submitted on EDGAR rather than reports furnished to the registrant when providing disclosure about Section 16(a) compliance.<sup>373</sup> Finally, the amendments to Item 407 clarify the applicable auditing standard and the disclosure requirements for the compensation committees of EGCs.<sup>374</sup>

The amendments to Item 401, Item 405, and Item 407 clarify and streamline existing disclosure requirements, and in that respect are expected to marginally reduce compliance costs for registrants. We estimate that the amendments will reduce the paperwork burden for each affected form by 0.5 hours. We expect that Form S-1, Form S-4, Form S-11, Form 8-K, Form 10, Form 10-K, and Form 10-Q will be affected by this amendment.

##### d. Exhibits

###### i. Information Omitted From Exhibits

We are adopting several amendments to Item 601 of Regulation S-K, as well as the exhibit requirements of certain of the Commission's disclosure forms to which Item 601 does not apply.<sup>375</sup> This includes exhibits required by certain of the Commission's disclosure forms related to investment companies.<sup>376</sup> Many of these amendments affect provisions related to the Commission's confidential treatment process.<sup>377</sup> As discussed in more detail below, we expect the annual internal burden hours and professional costs devoted to the confidential treatment process to decrease each time exhibit information is omitted or redacted in reliance on the amendments.

###### (1) Confidential Information in Material Contracts

The amendments will, in most cases, eliminate the need for registrants to submit a CTR when they redact information from material contracts in reliance on the FOIA exemption for information that likely would result in competitive harm to the registrant if disclosed.<sup>378</sup> Accordingly, our assumption is that implementation of the amendments will significantly reduce the number and corresponding costs of confidential treatment requests received by the Commission. However, it is difficult to predict with certainty the magnitude of the reduction because, as noted, the Commission and its staff will retain the discretion to comment on

<sup>373</sup> See *supra* Section II.B.2(b).

<sup>374</sup> See *supra* Section II.B.3.

<sup>375</sup> See *supra* Sections II.A.2. and II.B.5.

<sup>376</sup> See *id.*

<sup>377</sup> *Id.*

<sup>378</sup> 5 U.S.C. 552(b)(4). See *supra* note 45.

a registrant's redactions from its exhibits and, where appropriate, request an analysis similar to the competitive harm analysis that is currently required as part of the existing CTR application process.<sup>379</sup> If such a request is made, a registrant would incur costs to prepare and provide this analysis that may be on par with the costs typically associated with the existing CTR application process.<sup>380</sup> Although such costs would somewhat offset the reduction in burden resulting from the amendments, we believe that, in the aggregate, the amendments will nevertheless result in significant savings in time and money.

For purposes of the PRA, we consider the time and cost to prepare and submit a confidential treatment request to be part of the paperwork burden associated with preparing and filing the related disclosure form. We estimate that the elimination of the need to prepare and submit a confidential treatment request in reliance on these amendments will reduce internal burden hours by ten hours per request for an estimated 20% of registrants that prepare the confidential treatment request without relying on outside counsel, and reduce external costs by \$4,000 per request<sup>381</sup> for an estimated 80% of registrants that retain outside counsel for this work.

In fiscal year 2018, over 90% of the CTR applications that were received by the Commission related to material contracts filed as exhibits requesting confidential treatment on the basis of FOIA exemption (b)(4),<sup>382</sup> in the following proportions: 39% were filed for Form 10-Q, 22% for Form 10-K, 12% for Form 8-K, 12% for Form S-1, 0% for Form S-3, 1% for Form S-4, 0% for Form S-11, 3% for Form 20-F, 1% for Form 10, 2% for Form F-1, 0% for Form F-3, and 0% for Form F-4. We are therefore ascribing changes in

paperwork burdens and costs to these forms in these same proportions.

### (2) Schedules and Attachments to Exhibits

The adoption of new Item 601(a)(5) in Regulation S-K<sup>383</sup> will permit registrants to omit entire schedules and attachments to exhibits required by Item 601, so long as the omitted schedules and attachments contain no material information and the omitted information is not otherwise disclosed in the exhibit or the disclosure document. The threshold for omission under new Item 601(a)(5) is lower than for omission under the amendment to Item 601(b)(10) discussed above, because the omission of schedules and attachments to exhibits under Item 601(a)(5) is not conditioned on the risk of the registrant suffering competitive harm if the information were to be disclosed. In addition to new Item 601(a)(5), we are adopting analogous amendments to Item 1016 of Regulation M-A,<sup>384</sup> Form 20-F,<sup>385</sup> Item 1.01 of Form 8-K,<sup>386</sup> certain investment company registration forms,<sup>387</sup> and Form N-CSR,<sup>388</sup> thereby allowing registrants to omit immaterial schedules and attachments to exhibits required by those other rules and forms.

For purposes of the Paperwork Reduction Act, we assume these amendments will result in some reduction in burden associated with the omission of immaterial schedules and attachments to exhibits, where applicable. In order to calculate the impact of these amendments, we considered as a baseline all exhibits with schedules and attachments that are currently filed under Item 601 of Regulation S-K, Item 1016 of Regulation M-A, Form 20-F, Item 1.01 of Form 8-K, and applicable investment company forms.<sup>389</sup> We did not include in this total, however, exhibits filed under Item 601(b)(2) of Regulation S-K, as that Item already permits registrants to omit immaterial schedules and attachments to required exhibits.

We then sought to estimate the percentage of all such schedules and attachments that contain no material information and for which the registrant

has not otherwise disclosed such information elsewhere in the exhibit or disclosure filing. However, we are unable to reliably estimate the volume of schedules and attachments that could be omitted under these amendments, and therefore how many potential confidential treatment requests would be unnecessary, because this would depend, in part, on whether the schedules contain material information. As a result, there is no practicable way for us to determine with confidence which information in those attachments and schedules is immaterial and therefore eligible to be omitted. In any event, we believe the impact of the amendments on registrants' paperwork burden will be relatively minor, particularly in comparison to the impact of our amendments to 601(b)(10)(iv) and parallel amendments to Form 20-F, Item 1.01 of Form 8-K, and various investment company forms. Accordingly, while there will be some reduction in burden associated with these amendments, we do not believe the reduction will be significant enough to warrant an adjustment to our burden estimates. Consistent with the view stated in the Proposing Release, we believe this approach to be advisable in order to avoid overestimating the decrease in paperwork burden.

### (3) Personally Identifiable Information

The adoption of new Item 601(a)(6) in Regulation S-K will permit registrants to omit PII from their exhibits without submitting a confidential treatment request.<sup>390</sup> In addition, we are adopting analogous amendments to Item 1016 of Regulation M-A,<sup>391</sup> Form 20-F,<sup>392</sup> Item 1.01 of Form 8-K,<sup>393</sup> certain investment company registration forms,<sup>394</sup> and Form N-CSR.<sup>395</sup>

For purposes of the Paperwork Reduction Act, we assume the amendments will result in some incremental reduction in burden, although we do not believe the reduction will be significant enough to warrant an additional adjustment to our burden estimates.

The exemption in FOIA that corresponds most closely to PII is FOIA Exemption 6, which covers information that, if disclosed, "would constitute a clearly unwarranted invasion of

<sup>379</sup> See *supra* Section II.A.2.

<sup>380</sup> We recognize that there will remain some burden associated with preparing redacted exhibits even if a CTR application is not required (for example, a registrant's determination of which terms in a material contract to redact involves time and effort, particularly if the registrant must negotiate with its counterparty to the contract regarding which terms to redact and which to make public; there may also be additional costs if outside legal advisors are involved). For that reason, when calculating the expected reduction in PRA burden, we did not make any adjustments to the burden associated with preparing redacted exhibits.

<sup>381</sup> The \$4,000 cost estimate is calculated as follows: 10 hours × \$400 per hour of outside counsel work = \$4,000.

<sup>382</sup> See *supra* note 378. Less than 1% of the CTR applications that were received in fiscal year 2018 were related to exhibits filed with Investment Company Act forms. Accordingly, while there will be some reduction in burden associated with the Investment Company Act forms, we do not believe the reduction will be significant enough to warrant an adjustment to our burden estimates.

<sup>383</sup> See *supra* Section II.B.5.b.i.

<sup>384</sup> See *supra* Section II.B.5.b.i., discussing the amended instructions to Item 1016 of Regulation M-A.

<sup>385</sup> See the Instructions to Exhibits in Form 20-F, as amended.

<sup>386</sup> See new Instruction 4 to Item 1.01 of Form 8-K.

<sup>387</sup> These are exhibits filed pursuant to Forms N-1A, N-2, N-3, N-4, N-5, N-6, N-14, N-8B-2, and S-6.

<sup>388</sup> See *supra* Section II.B.5.b.i.

<sup>389</sup> *Id.*

<sup>390</sup> See *supra* Section II.B.5.b.ii.

<sup>391</sup> See *supra* Section II.B.5.b.i., discussing the amended instructions to Item 1016 of Regulation M-A.

<sup>392</sup> See the Instructions to Exhibits in Form 20-F, as amended.

<sup>393</sup> See new Instruction 4 to Item 1.01 of Form 8-K.

<sup>394</sup> See *supra* note 387.

<sup>395</sup> See *supra* Section II.B.5.b.ii.

personal privacy.”<sup>396</sup> In recent years, the Commission has issued very few confidential treatment orders in reliance on FOIA Exemption 6. For example, in fiscal year 2018, only 14 confidential treatment requests were received by the Commission, out of which 10 were granted for documents containing PII. Presumably, most registrants are currently taking advantage of the existing staff position that PII may be omitted without filing a confidential treatment request. As a result, we do not expect that codifying this accommodation will significantly alter existing disclosure practices.

ii. Material Contracts Exhibits (Item 601(b)(10)(i))

The amendment to Item 601(b)(10)(i) limits the two-year look back filing requirement for material contracts to newly reporting registrants.<sup>397</sup> Registrants that are not newly reporting registrants will not be required to comply with this filing requirement and thus will incur reduced compliance burdens. However, we believe that the current burden associated with the two-year look back requirement is minimal. Therefore, the amendments are not expected to result in a significant reduction of the paperwork burden associated with the affected forms. We estimate that the paperwork burden will be reduced by 0.5 hours for each form affected by the amendment. We expect that Form 10, Form 10-K, Form 20-F, Form S-1, Form S-4, Form F-1, Form F-3, Form F-4, Form S-11, and Form SF-1 will be affected by this amendment.

2. Amendments Expected To Increase Burdens

a. Registration Statement and Prospectus Provisions (Item 501(b))

We are amending Item 501(b) to require disclosure on the cover page of the prospectus of any national securities exchange where the securities being offered are listed or, if not listed, the principal United States market or markets for the securities being offered and the corresponding trading symbols, if any.<sup>398</sup> The amendments will incrementally increase the compliance burden on registrants by requiring them to provide disclosure about trading markets other than national exchanges. Because we are limiting the incremental disclosure to those trading markets where the registrant, through the engagement of a registered broker-dealer, has actively sought and achieved

quotation, we believe this information should be readily available to registrants and impose only a minimal paperwork burden.

Accordingly, we estimate that the amendment will slightly increase the paperwork burden associated with each affected form by 0.25 hours. We expect that Form S-1, Form S-3, Form S-4, Form S-11, Form F-1, Form F-3, Form F-4, Form SF-1, and Form SF-3 will be affected by this amendment.

b. Exhibits (Item 601(b)(4)(vi))

New Item 601(b)(4)(vi) requires registrants to file an Item 202 description of their Exchange Act registered securities as an exhibit to Form 10-K.<sup>399</sup> Similarly, we are amending the instructions to exhibits in Form 20-F to provide a parallel requirement.<sup>400</sup>

We expect that the new requirements under Item 601(b)(4)(vi) will slightly increase the paperwork burden on registrants because registrants will be required to provide a description of registered securities annually. However, registrants will be able to incorporate by reference and hyperlink to prior disclosure if the information called for by Item 202 remains unchanged from prior years, thus mitigating any increase in the anticipated burden. Accordingly, we estimate the amendments will increase the paperwork burden associated with Form 10-K and Form 20-F by 0.5 hours.

c. Manner of Delivery

New Rule 406, new Item 601(b)(104), new paragraph 104 to “Instructions as to Exhibits” of Form 20-F and new Instruction 17 to “Information To Be Filed on this Form” of Form 40-F require registrants to tag every data point on the cover pages of Form 10-K, Form 10-Q, Form 8-K, Form 20-F, and Form 40-F using Inline XBRL, including certain new data points added pursuant to the amendments.<sup>401</sup> Although expanded data tagging will result in an increase in the burden associated with related forms, we note that registrants are already required to tag certain cover page information as well as financial statement information. For this reason, we believe most registrants already have developed the internal resources or engaged outside professionals to assist them in complying with existing data tagging requirements.<sup>402</sup> In this respect, we do

not believe the cover page tagging requirement will result in significant additional burdens for registrants.

Accordingly, we estimate that the requirement to tag additional cover page items will impose an increased paperwork burden of one hour for each affected form. We expect that Form 10-K, Form 10-Q, Form 8-K, Form 20-F, and Form 40-F will be affected by the new rules and form amendments.

As described in more detail above, we are adopting amendments to Regulation S-T and certain of our forms used by investment companies to require investment companies to submit filings on those forms in HTML format and to include a hyperlink from each exhibit identified in the exhibit index of such forms. We anticipate that these amendments will increase the burdens and costs for investment companies to prepare and file the affected forms, but we believe the associated burdens will be small as an investment company preparing a filing, will already be preparing the exhibits and exhibit index for such filing and will have readily available all of the information necessary to create a hyperlink. For purposes of the PRA, we assumed that the average burden hours of requiring exhibit hyperlinks will vary based on the number of exhibits that are included with a filing. Based on the average and median number of exhibits shown in Table 3 above and the staff’s experience, we estimate that the average burden for an investment company to hyperlink to exhibits will be one hour per response for each of the affected forms.

3. Amendments Not Expected to Meaningfully Affect Burdens

a. Registration Statement and Prospectus Provisions (Item 501(b), Item 503(c), Item 508 and Item 512)

The amendments to Item 501(b)(1), Item 501(b)(3), and Item 501(b)(10) will, respectively, streamline company name disclosure requirements, explicitly allow registrants to include a clear statement on the cover page of the prospectus that the offering price will be determined by a particular method or formula (and require a cross reference to the offering price method or formula

are currently required to submit financial statement information in XBRL and open-end management investment companies that are currently required to submit risk/return summary XBRL data to transition to Inline XBRL on a phased-in basis. The date of mandatory compliance with the Inline XBRL rules depends on the type of filer. See Inline XBRL Adopting Release, *supra* note 258. Because the Commission estimated the burden associated with the transition to Inline XBRL in that release, for purposes of this PRA analysis we only consider the incremental burden corresponding to our adoption of the amendments discussed in this release.

<sup>396</sup> 5 U.S.C. 552(b)(6).

<sup>397</sup> See *supra* Section II.B.5.c.

<sup>398</sup> See *supra* Section II.B.4.a.iii.

<sup>399</sup> See *supra* Section II.B.5.a.

<sup>400</sup> See *id.*

<sup>401</sup> See *supra* Section II.B.7.a.

<sup>402</sup> As discussed above, the Commission recently adopted rules requiring operating companies that

disclosure), and permit registrants to exclude some portion of the legend relating to state law in the prospectus for an offering that is not prohibited by state blue sky law.<sup>403</sup> The amendments to Item 503(c) relocate the current risk factor disclosure requirements to Subpart 100 and eliminate the risk factor examples without substantively changing the underlying disclosure requirements.<sup>404</sup> The amendment to Item 508 defines the term “sub-underwriter” to clarify one aspect of the required disclosure about the plan of distribution for a registered securities offering.<sup>405</sup> The amendments to Item 512 eliminate certain undertakings that are redundant or obsolete.<sup>406</sup>

We believe these amendments will not meaningfully affect the paperwork burden associated with the affected forms because these amendments modernize and clarify certain requirements and do not substantively change the required disclosure. Therefore, we are not making any adjustments to the paperwork burden of affected forms due to these amendments.

b. Incorporation by Reference

We are adopting amendments to simplify and modernize the rules and forms governing incorporation by reference. Under the amendments, certain existing requirements for incorporation by reference have been consolidated into Rule 411, Rule 12b-23, Rule 0-4, and Rule 0-6.<sup>407</sup> The

amendments also eliminate several redundant or outdated requirements, including the rescission of rules under the Investment Company Act.<sup>408</sup> In addition, we are adopting amendments to our rules and forms that prohibit incorporation by reference or cross-referencing, in the financial statements, to information outside of the financial statements.<sup>409</sup> These amendments are expected to decrease reporting burdens associated with incorporating information by reference in Commission filings, leading to an estimated 0.5 hour reduction in paperwork burden per affected form. However, this decrease will be offset by an estimated 0.5 hour increase in paperwork burden per affected form due to the amendments requiring registrants to include hyperlinks to information incorporated by reference when that information is available on EDGAR.<sup>410</sup> Accordingly, we are not making any adjustments to the paperwork burden of affected forms due to these amendments.

D. Burden and Cost Estimates to the Amendments

As discussed below, we expect that the amendments will, in the aggregate, reduce the paperwork burden on respondents. The change in burden, however, will differ depending on the form because not all of the amendments apply to each form.

These estimates represent the average burden for all registrants, both large and small. In deriving our estimates, we

recognize that the burdens will likely vary among individual registrants based on a number of factors, including the nature of their business.

The burden estimates were calculated by multiplying the estimated number of annual responses by the estimated average amount of time it would take a registrant to prepare and review disclosure required under the amendments. The portion of the burden carried by outside professionals is reflected as a cost, while the portion of the burden carried by the registrant internally is reflected in hours.

1. Form 10-K and Form 10-Q; Schedule 14A and Schedule 14C

The amendments are estimated to reduce the paperwork burdens associated with Form 10-K<sup>411</sup> and Form 10-Q as well as Schedule 14A and Schedule 14C.<sup>412</sup> For purposes of the PRA, we estimate that 75% of the burden of preparation for these Exchange Act reports is carried by the registrant internally and that 25% of the burden of preparation is carried by outside professionals retained by the company at an average cost of \$400 per hour.<sup>413</sup>

Table 4 below illustrates the total annual compliance burden, in hours and in costs,<sup>414</sup> of the affected collections of information resulting from the amendments.<sup>415</sup>

TABLE 4—INCREMENTAL PAPERWORK BURDEN UNDER THE AMENDMENTS FOR EXCHANGE ACT FORMS

	Current annual responses	Estimated number of affected responses	Current burden hours	Change in burden hours	Change in company hours	Change in professional hours	Change in professional costs
10-K .....	8,137	8,137	14,217,344	(31,040)	(21,872)	(9,168)	(\$3,667,150)
10-Q .....	22,907	22,907	3,241,957	(61,777)	(43,853)	(17,924)	(7,169,600)
8-K .....	118,387	118,387	685,255	176,170	132,903	43,267	17,306,800

<sup>403</sup> See *supra* Section II.B.4.a. The amendments also streamline 501(b) by combining paragraphs (b)(10) and (b)(11) without substantive change.

<sup>404</sup> See *supra* Section II.B.4.b.

<sup>405</sup> See *supra* Section II.B.4.c.

<sup>406</sup> See *supra* Section II.B.4.d.

<sup>407</sup> See *supra* Section II.B.6.

<sup>408</sup> *Id.*

<sup>409</sup> See *supra* Section II.A.3.

<sup>410</sup> See *supra* Section II.B.6.b.ii.

<sup>411</sup> Schedules 14A and 14C require disclosure under Subpart 400 of Regulation S-K. This disclosure is often incorporated, in relevant part, into Part III of a registrant’s Form 10-K. Therefore, our burden estimates for Form 10-K contemplate

that Part III disclosure may be incorporated by reference to Schedules 14A or 14C.

<sup>412</sup> Schedule 14A requires that registrants, under certain circumstances, provide disclosure under Item 303. Our burden estimate for Schedule 14A assumes that registrants will duplicate the disclosure provided under this Item in the most recent Form 10-K and/or Form 10-Q.

<sup>413</sup> We recognize that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis we estimate that such costs will be an average of \$400 per hour. This estimate is based on consultations with several registrants, law firms and other persons who regularly assist registrants in preparing and filing reports with the Commission.

<sup>414</sup> For convenience, the estimated hour and cost burdens in the tables in this section have been rounded to the nearest whole number.

<sup>415</sup> The burdens associated with the amendments to the forms listed in Table 4, other than the confidential treatment request amendments, have been estimated by assuming that 75% of the burden is borne by the company and 25% is borne by outside counsel at \$400 per hour. The burdens associated with submitting confidential treatment requests in connection with the forms listed in Table 4 have been estimated by assuming that the average request requires approximately ten hours of preparation and that 20% of the burden is borne by the company and 80% of the burden is borne by outside counsel at \$400 per hour.

2. Form S-1, Form S-3, Form S-4, Form F-3, Form F-4, Form SF-1, Form SF-3, Form 10, and Form 20-F

The amendments are estimated to reduce the paperwork burden associated with Form S-1, Form S-3, Form S-4, Form S-11, Form F-1, Form F-4, Form

10, and Form 20-F. For registration statements on Form 10, Form S-1, Form S-3, Form S-4, Form F-1, Form F-3, Form F-4, Form SF-1, and Form SF-3, and Exchange Act report Form 20-F, we estimate that 25% of the burden of preparation is carried by the company internally and that 75% of the burden

of preparation is carried by outside professionals retained by the company at an average cost of \$400 per hour.

Table 5 below illustrates the total annual compliance burden, in hours and in costs, of the affected collections of information resulting from the amendments.<sup>416</sup>

TABLE 5—INCREMENTAL PAPERWORK BURDEN UNDER THE AMENDMENTS FOR REGISTRATION STATEMENTS

	Current annual responses	Estimated number of affected responses	Current burden hours	Change in burden hours	Change in company hours	Change in professional hours	Change in professional costs
S-1	901	901	150,998	(5,670)	(1,348)	(4,322)	(\$1,728,725)
S-3	1,657	1,657	196,930	(414)	(104)	(310)	(124,000)
S-4	551	551	565,079	(3,033)	(751)	(2,282)	(912,625)
S-11	64	64	12,514	(304)	(76)	(228)	(91,200)
SF-3	71	71	24,548	18	4	13	5,325
F-1	63	63	26,980	(548)	(123)	(425)	(169,925)
F-3	112	112	4,467	(28)	(7)	(21)	(8,400)
F-4	39	39	14,245	(107)	(27)	(80)	(32,175)
10	216	216	11,774	(880)	(217)	(664)	(265,400)
20-F	725	725	480,226	(1,991)	(480)	(1,511)	(604,575)
40-F	132	132	14,187	198	50	148	59,200

TABLE 6—CURRENT AND REVISED BURDENS UNDER THE AMENDMENTS FOR SECURITIES ACT AND EXCHANGE ACT FORMS

	Current burden		Revised burden	
	Burden hours (A)	Costs (B)	Burden hours (C)	Costs (D)
10-K	14,217,344	\$1,896,280,869	14,195,472	\$1,892,613,719
10-Q	3,241,957	432,290,354	3,198,104	425,120,754
8-K	685,255	91,367,630	818,158	108,674,430
S-1	150,998	181,197,300	149,650	179,468,575
S-3	196,930	236,322,036	196,826	236,198,036
S-4	565,079	678,094,704	564,328	677,182,079
S-11	12,514	15,016,968	12,438	14,925,768
SF-3	24,548	29,457,900	24,552	29,463,225
F-1	26,980	32,375,700	26,857	32,205,775
F-3	4,760	5,712,000	4,753	5,703,600
F-4	14,245	17,093,700	14,218	17,061,525
10	11,774	14,128,888	11,558	13,863,488
20-F	480,226	576,270,600	479,746	575,666,025
40-F	14,187	17,025,360	14,237	17,084,560

3. Form 8-A, Form 10-D, Form 40-F, Form F-7, Form F-8, Form F-10, and Form F-80

The amendments to Form 8-A,<sup>417</sup> Form 10-D, Form F-7,<sup>418</sup> Form F-8,<sup>419</sup> Form F-10, and Form F-80<sup>420</sup> are not expected to meaningfully reduce the associated paperwork burden for these forms. Accordingly, we have not included a tabular presentation of the impact on the total annual compliance burden of these forms as a result of these amendments.

4. Form S-6, Form N-1A, Form N-2, Form N-3, Form N-4, Form N-5, Form N-6, Form N-14, Form N-8B-2, and Form N-CSR

The amendments to Regulation S-T that will require investment companies filing on Forms S-6, N-1A, N-2, N-3, N-4, N-5, N-6, N-14, N-8B-2, or N-CSR to submit these documents in HTML format and to include a hyperlink to each exhibit identified in the exhibit index of these documents are expected to increase the burdens and costs for investment companies that

prepare and file these registration statements and reports. For purposes of the PRA, we estimated the average burden for an investment company to hyperlink to exhibits based on the median number of exhibits that are filed with an affected form.

The table below shows the changes in professional costs and burden hours from the burden estimates currently approved by OMB and the new burden estimates under the amendments. The burden estimates were calculated by multiplying the estimated number of

<sup>416</sup> The burdens associated with the amendments to the forms listed in Table 5, other than the confidential treatment request amendments, have been estimated by assuming that 25% of the burden is borne by the company and 75% is borne by outside counsel at \$400 per hour. The burdens

associated with submitting confidential treatment requests in connection with the forms listed in Table 5 have been estimated by assuming that the average request requires approximately ten hours of preparation and that 20% of the burden is borne by

the company and 80% of the burden is borne by outside counsel at \$400 per hour.

<sup>417</sup> 17 CFR 249.208a.

<sup>418</sup> 17 CFR 239.37.

<sup>419</sup> 17 CFR 239.38.

<sup>420</sup> 17 CFR 239.41.

responses by the estimated average amount of time—one hour—it would take an issuer to prepare and review the exhibit hyperlinks. The portion of the burden carried by outside professionals

is reflected as a cost, while the portion of the burden carried by the issuer internally is reflected in hours. For purposes of the PRA, we estimate that 25% of the burden of preparation is

carried by the registrant internally and that 75% of the burden of preparation is carried by outside professionals retained by the investment company at an average cost of \$400 per hour.<sup>421</sup>

TABLE 7—INCREMENTAL PAPERWORK BURDEN UNDER THE AMENDMENTS TO FORMS FOR INVESTMENT COMPANIES

Form	Current annual responses (A)	Estimated number of affected responses	Current burden hours	Change in burden hours	Change in company hours	Change in professional hours	Change in professional costs
S-6 .....	2,498	2,498	106,620	2,498	625	1,874	\$749,600
N-1A .....	6,002	6,002	1,596,749	6,002	1,501	4,502	1,800,800
N-2 .....	166	166	73,250	166	42	125	50,000
N-3 .....	20	20	2,500	20	5	15	6,000
N-4 .....	1,653	1,653	343,117	1,653	413	1,240	496,000
N-5 .....	1	1	117	1	0	1	400
N-6 .....	472	472	85,269	472	118	354	141,600
N-14 .....	192	192	97,280	192	48	144	57,600
N-CSR .....	6,898	6,898	174,085	6,898	1,725	5,174	2,069,600

TABLE 8—CURRENT AND REVISED BURDENS UNDER THE AMENDMENTS TO FORMS FOR INVESTMENT COMPANIES

Form	Current burden		Revised burden	
	Burden hours (A)	Costs (B)	Burden hours (C)	Costs (D)
S-6 .....	106,620	\$67,359,556	107,245	\$68,108,956
N-1A .....	1,596,749	129,338,408	1,598,250	131,139,008
N-2 .....	73,250	4,668,396	73,292	4,718,196
N-3 .....	2,500	164,144	2,505	168,944
N-4 .....	343,117	36,308,889	343,530	36,804,789
N-5 .....	117	10,000	117	10,400
N-6 .....	85,269	5,316,892	85,387	5,364,092
N-14 .....	97,280	4,498,000	97,328	4,517,200
N-8B2 .....	40	40,000	88	40,300
N-CSR .....	174,085	3,129,984	175,810	5,199,384

**VIII. Final Regulatory Flexibility Act Analysis**

This Final Regulatory Flexibility Analysis (“FRFA”) has been prepared in accordance with the Regulatory Flexibility Act (“RFA”).<sup>422</sup> It relates to amendments that modernize and simplify certain disclosure requirements in Regulation S-K and related rules and forms to implement Section 72003 of the FAST Act and provide consistent incorporation by reference and hyperlinking requirements in the rules and forms applicable to investment companies and investment advisers.

*A. Need for, and Objectives of, the Amendments*

The purpose of the amendments is to modernize and simplify Commission disclosure requirements in a manner that reduces costs and burdens on companies while still providing all material information. Specifically, the

amendments modernize and simplify these disclosure requirements by clarifying, consolidating, relocating and eliminating, or updating various Commission rules that govern public company disclosure. The amendments also modernize the rules by requiring cover page data to be tagged in a machine-readable format and requiring hyperlinks to be included in some documents filed on EDGAR. The amendments largely implement the staff’s recommendations in the FAST Act Report, as required by Section 72003(d) of the FAST Act. In addition, to provide for a consistent set of rules to govern incorporation by reference and hyperlinking, the Commission is also adopting parallel amendments to several rules and forms applicable to investment companies and investment advisers.<sup>423</sup>

*B. Significant Issues Raised by Public Comments*

In the Proposing Release, the Commission requested comment on any aspect of the Initial Regulatory Flexibility Analysis (“IRFA”), including how the proposed rule and form amendments can achieve their objective while lowering the burden on small entities, the number of small entities that would be affected by the proposed rule and form amendments, the existence or nature of the potential effects of the proposed amendments on small entities discussed in the analysis, and how to quantify the effects of the proposed amendments. We did not receive comments specifically addressing the IRFA. We did, however, receive one comment letter that addressed an aspect of the proposed amendments that could potentially affect small entities. Specifically, one

<sup>421</sup> We recognize that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis, we estimate that such costs would be an average of \$400 per hour. These

estimates are based on our estimates for the parallel requirement for operating companies. See Exhibit Hyperlinks Adopting Release, *supra* note 10, at 14139.

<sup>422</sup> 5 U.S.C. 601 *et seq.*

<sup>423</sup> The need for, and objectives of, the final rules are discussed in more detail throughout this release, particularly in Sections I and II, *supra*.

commenter who supported the proposal to permit registrants to redact confidential information in some circumstances without submitting a confidential treatment request noted the benefits that would accrue in particular to smaller reporting companies.<sup>424</sup> This commenter stated that the time and expense involved in preparing requests for confidential treatment disproportionately burdens smaller reporting companies compared to larger companies because smaller companies have a lower threshold for determining whether a contract is material and must be publicly filed. In addition, the commenter asserted that the legal fees associated with the preparation of a confidential treatment request can be “daunting” for these companies.<sup>425</sup>

### C. Small Entities Subject to the Amendments

The amendments will apply to some registrants that are small entities. The RFA defines “small entity” to mean “small business,” “small organization,” or “small governmental jurisdiction.”<sup>426</sup> For purposes of the RFA, under our rules, an issuer, other than an investment company or an investment adviser, is a “small business” or “small organization” if it had total assets of \$5 million or less on the last day of its most recent fiscal year and is engaged or proposing to engage in an offering of securities that does not exceed \$5 million.<sup>427</sup> An investment company, including a business development company,<sup>428</sup> is considered to be a “small business” if it, together with other investment companies in the same group of related investment companies, has net assets of \$50 million or less as of the end of its most recent fiscal year.<sup>429</sup> An investment adviser generally is a small entity if it: (1) Has assets under management having a total value of less than \$25 million; (2) did not have total assets of \$5 million or more on the last day of the most recent fiscal year; and (3) does not control, is not controlled by, and is not under common control with another investment adviser that has assets under

management of \$25 million or more, or any person (other than a natural person) that had total assets of \$5 million or more on the last day of its most recent fiscal year.<sup>430</sup>

We estimate that there are 1,171 issuers that file with the Commission, other than investment companies and investment advisers, that may be considered small entities.<sup>431</sup> In addition, we estimate that, as of June 2018, there were 116 investment companies that would be considered small entities.<sup>432</sup> Finally, we estimate that, as of June 2018, there were approximately 618 investment advisers that would be considered small entities.<sup>433</sup>

### D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

As noted above, the purpose of the amendments is to modernize and simplify the Commission’s disclosure requirements and provide consistent incorporation by reference and hyperlinking rules for registrants, including investment companies and investment advisers. The majority of the amendments are expected to have a minor effect on existing reporting, recordkeeping and other compliance burdens for all issuers, including small entities.<sup>434</sup>

<sup>430</sup> See Investment Advisers Act Rule 0–7(a) [17 CFR 275.0–7(a)].

<sup>431</sup> This estimate is based on staff analysis of issuers, excluding co-registrants, with EDGAR filings of Form 10–K, 20–F and 40–F, or amendments, filed during the calendar year of January 1, 2018 to December 31st, 2018. Analysis is based on data from XBRL filings, Compustat, and Ives Group Audit Analytics. The methodology used to estimate the number of small entities builds upon the methodology used in the Proposing Release. In the Proposing Release, the number of small entities excluded entities that filed Form 40–F and amendments to Forms 10–K, 20–F, and 40–F and was based on entities with fiscal periods ending between January 31, 2015 and January 31, 2016. See Proposing Release, *supra* note 5, at 7.

<sup>432</sup> This estimate is based on staff review of data obtained from Morningstar Direct as well as data reported on Forms N–CEN, N–Q, 10–K and 10–Q filed with the Commission as of June 2018.

<sup>433</sup> This estimate is based on Commission-registered investment adviser responses to Form ADV, Item 5.F and Item 12.

<sup>434</sup> We recognize that the fixed costs of disclosure requirements typically constitute a higher percentage of revenues for smaller companies than for larger companies. However, the benefits of disclosure may be greater for smaller companies because information asymmetries between investors and managers of smaller companies are typically higher than for larger, more seasoned companies with a large following. See, e.g., R. Frankel and X. Li, *Characteristics of a firm’s information environment and the information asymmetry between insiders and outsiders*, 37 J. Acct. Econ. 229, 229–259 (June 2004). See also L. Cheng, S. Liao, and H. Zhang, *The Commitment Effect versus Information Effect of Disclosure—Evidence from Smaller Reporting Companies*, 88 Acct. Rev. 1239, 1239–1263 (2013).

Many of the amendments simplify and streamline existing disclosure requirements in ways that are expected to reduce compliance burdens. Some of the amendments, like those that impose new data tagging,<sup>435</sup> hyperlinking,<sup>436</sup> or disclosure requirements<sup>437</sup> will increase compliance costs for registrants, and some of these costs could disproportionately affect small entities. For example, smaller investment company registrants currently reporting in ASCII are more likely to be impacted by the mandated use of HTML. While investment companies that file forms in ASCII will incur costs to switch to HTML, in addition to the costs of hyperlinking to exhibits, we expect that the burden to switch from ASCII to HTML will not be significant because the software tools to file in HTML format are now widely used and available at a minimal cost. In addition, during calendar year 2018, approximately 10% of the forms that will be affected by the amendments were filed in ASCII. The limited use of ASCII to file these forms indicates that the final amendments will affect only a limited number of registrants on a one-time basis.

Overall, for the reasons discussed elsewhere in this release, we do not expect these additional costs to be significant relative to existing compliance costs. Moreover, we expect that the benefits of the amended confidential treatment rules accruing to smaller reporting companies, who may be disproportionately burdened by the time and expense involved in preparing requests for confidential treatment,<sup>438</sup> will offset some of their compliance costs that are estimated to increase because of the amendments. The professional skills necessary to comply with the amendments include legal, accounting, and information technology skills.<sup>439</sup>

### E. Agency Action To Minimize Effect on Small Entities

The RFA directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant adverse impact on small

<sup>435</sup> See, e.g., *supra* Section II.B.7.a. (Tagging Cover Page Data).

<sup>436</sup> See, e.g., *supra* Section II.B.7.b. (Exhibit Hyperlinks and HTML Format for Investment Companies).

<sup>437</sup> See, e.g., *supra* Section II.B.4.a.iii. (Market for the Securities (Item 501(b)(4)).

<sup>438</sup> See *supra* note 424.

<sup>439</sup> The final rules are discussed in detail in Section II, *supra*. We discuss the economic impact, including the estimated compliance costs and burdens, of the final rules in Section VI (Economic Analysis) and Section VII (Paperwork Reduction Act), *supra*.

<sup>424</sup> See letter from Reed Smith.

<sup>425</sup> The commenter also mentioned emerging growth biotechnology companies undertaking an IPO, which it stated “are hardest hit by the arduous confidential treatment process.” See *id*.

<sup>426</sup> 5 U.S.C. 601(6).

<sup>427</sup> See Securities Act Rule 157 [17 CFR 230.157] and Exchange Act Rule 0–10(a) [17 CFR 240.0–10(a)].

<sup>428</sup> Business development companies are a category of closed-end investment company that are not registered under the Investment Company Act [15 U.S.C. 80a–2(a)(48) and 80a–53–64].

<sup>429</sup> See Investment Company Act Rule 0–10(a) [17 CFR 270.0–10(a)].

entities. In connection with the amendments, we considered the following alternatives:

- Establishing different compliance or reporting requirements that take into account the resources available to small entities;
- clarifying, consolidating, or simplifying compliance and reporting requirements under the rules for small entities;
- using performance rather than design standards; and
- exempting small entities from all or part of the requirements.

We believe the amendments clarify, consolidate and simplify compliance and reporting requirements for small entities and other registrants. As discussed above, we believe the majority of the amendments simplify and streamline disclosure requirements in ways that are expected to reduce compliance burdens.<sup>440</sup> We do not believe that the amendments will impose any significant new compliance obligations. Accordingly, we generally do not believe it is necessary to establish different compliance and reporting requirements or timetables or to exempt small entities from all or part of the amendments.<sup>441</sup> We note in this regard that the Commission's existing disclosure requirements provide for scaled disclosure requirements and other accommodations for small entities, and the amendments would not alter these existing accommodations.

Finally, with respect to using performance rather than design standards, the amendments generally use design rather than performance standards in order to promote uniform filing requirements for all registrants. In some instances, the amendments modernize and simplify existing design standards. For example, the amendments to Item 303(a) emphasize the flexibility currently available to registrants with respect to the form of MD&A presentation.<sup>442</sup> In other instances, the amendments may result in additional flexibility when preparing disclosures. For example, new Item 601(a)(5) expands a registrant's ability to

<sup>440</sup> See *supra* Sections VI (Economic Analysis) and VII (Paperwork Reduction Act).

<sup>441</sup> As discussed above in Section V (Compliance Dates), the compliance date schedule for cover page tagging will be consistent with the scaled phase-in of Inline XBRL generally. Also, as discussed in Section V, we are adopting a compliance date of April 1, 2020 for registration statement and Form N-CSR filings to be made in HTML format and comply with the rule and form amendments pertaining to hyperlinks. We believe that this transition period will provide sufficient time for investment companies, regardless of size, to comply with the new requirements.

<sup>442</sup> See *supra* Section II.A.1.a. (Year-to-Year Comparisons (Instruction 1 to Item 303(a)).

omit schedules and attachments to exhibits that are not material.<sup>443</sup> As another example, the amendments to Item 102 clarify that the threshold for disclosure about registrants' physical properties is based on materiality.<sup>444</sup>

#### IX. Statutory Authority

We are adopting the rule and form amendments contained in this release under the authority set forth in Sections 7, 10, 19(a), and 28 of the Securities Act of 1933, as amended, Sections 3(b), 12, 13, 14, 15, 16, 23(a), and 36 of the Securities Exchange Act of 1934, as amended, Sections 6(c), 8, 24(a), 30, and 38 of the Investment Company Act of 1940, as amended, and Sections 204, 206A, 210, and 211 of the Investment Advisers Act of 1940, as amended.

#### List of Subjects in 17 CFR Parts 229, 230, 232, 239, 240, 249, 270, 274, and 275

Administrative practice and procedure, Reporting and recordkeeping requirements, Securities.

In accordance with the foregoing, we are amending title 17, chapter II of the Code of Federal Regulations as follows:

#### PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S-K

- 1. The authority citation for part 229 continues to read as follows:

**Authority:** 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z-2, 77z-3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78j-3, 78l, 78m, 78n, 78n-1, 78o, 78u-5, 78w, 78ll, 78 mm, 80a-8, 80a-9, 80a-20, 80a-29, 80a-30, 80a-31(c), 80a-37, 80a-38(a), 80a-39, 80b-11 and 7201 *et seq.*; 18 U.S.C. 1350; sec. 953(b), Pub. L. 111-203, 124 Stat. 1904 (2010); and sec. 102(c), Pub. L. 112-106, 126 Stat. 310 (2012).

#### § 229.10 [Amended]

- 2. Amend § 229.10 by:
  - a. Removing and reserving paragraph (d); and
  - b. Revising the entry for Item 503 in the Index of Scaled Disclosure Available to Smaller Reporting Companies in paragraph (f) to read "Prospectus summary."
- 3. Amend § 229.102 by revising the introductory text and Instructions 1 and 2 to to Item 102 to read as follows:

<sup>443</sup> See *supra* Section II.B.5.b.i. (Schedules and Attachments to Exhibits).

<sup>444</sup> See *supra* Section II.B.1. (Description of Property (Item 102)).

#### § 229.102 (Item 102) Description of property.

To the extent material, disclose the location and general character of the registrant's principal physical properties. In addition, identify the segment(s), as reported in the financial statements, that use the properties described. If any such property is not held in fee or is held subject to an encumbrance that is material to the registrant, so state and describe briefly how held.

*Instruction 1 to Item 102:* This item requires information that will reasonably inform investors as to the suitability, adequacy, productive capacity, and extent of utilization of the principal physical properties of the registrant and its subsidiaries, to the extent the described properties are material. A registrant should engage in a comprehensive consideration of the materiality of its properties. If appropriate, descriptions may be provided on a collective basis; detailed descriptions of the physical characteristics of individual properties or legal descriptions by metes and bounds are not required and shall not be given.

*Instruction 2 to Item 102:* In determining materiality under this Item, the registrant should take into account both quantitative and qualitative factors. See Instruction 1 to Item 101 of Regulation S-K (§ 229.101).

\* \* \* \* \*

- 4. Add § 229.105 to subpart 229.100 to read as follows:

#### § 229.105 (Item 105) Risk factors.

Where appropriate, provide under the caption "Risk Factors" a discussion of the most significant factors that make an investment in the registrant or offering speculative or risky. This discussion must be concise and organized logically. Do not present risks that could apply generically to any registrant or any offering. Explain how the risk affects the registrant or the securities being offered. Set forth each risk factor under a subcaption that adequately describes the risk. If the risk factor discussion is included in a registration statement, it must immediately follow the summary section. If you do not include a summary section, the risk factor section must immediately follow the cover page of the prospectus or the pricing information section that immediately follows the cover page. Pricing information means price and price-related information that you may omit from the prospectus in an effective registration statement based on Rule 430A (§ 230.430A(a) of this chapter).

The registrant must furnish this information in plain English. See § 230.421(d) of Regulation C of this chapter.

■ 5. Amend § 229.202 by removing the note at the start of the section, revising Instruction 3 under “Instructions to Item 202,” and adding “Note to § 229.202” to the end of the section.

The revision and addition read as follows:

**§ 229.202 (Item 202) Description of registrant’s securities.**

\* \* \* \* \*

*Instructions to Item 202:* \* \* \*

3. Section 305(a)(2) of the Trust Indenture Act of 1939, U.S.C. 77aaa *et seq.*, as amended (“Trust Indenture Act”), shall not be deemed to require the inclusion in a registration statement, prospectus, or annual report on Form 10–K of any information not required by this Item or Item 601(b)(4)(vi) of this chapter.

\* \* \* \* \*

**Note to § 229.202:** If the securities being described have been accepted for listing on an exchange, the exchange may be identified. The document should not, however, convey the impression that the registrant may apply successfully for listing of the securities on an exchange or that, in the case of an underwritten offering, the underwriters may request the registrant to apply for such listing, unless there is reasonable assurance that the securities to be offered will be acceptable to a securities exchange for listing.

■ 6. Amend § 229.303 by revising Instruction 1 under “Instructions to paragraph 303(a)” to read as follows:

**§ 229.303 (Item 303) Management’s discussion and analysis of financial condition and results of operations.**

\* \* \* \* \*

*Instructions to paragraph 303(a):* 1. The registrant’s discussion and analysis shall be of the financial statements and other statistical data that the registrant believes will enhance a reader’s understanding of its financial condition, changes in financial condition, and results of operations. Generally, the discussion shall cover the periods covered by the financial statements included in the filing and the registrant may use any presentation that in the registrant’s judgment enhances a reader’s understanding. A smaller reporting company’s discussion shall cover the two-year period required in Article 8 of Regulation S–X and may use any presentation that in the registrant’s judgment enhances a reader’s understanding. For registrants providing financial statements covering three years in a filing, discussion about the earliest of the three years may be

omitted if such discussion was already included in the registrant’s prior filings on EDGAR that required disclosure in compliance with Item 303 of Regulation S–K, provided that registrants electing not to include a discussion of the earliest year must include a statement that identifies the location in the prior filing where the omitted discussion may be found. An emerging growth company, as defined in Rule 405 of the Securities Act (§ 230.405 of this chapter) or Rule 12b–2 of the Exchange Act (§ 240.12b–2 of this chapter), may provide the discussion required in paragraph (a) of this Item for its two most recent fiscal years if, pursuant to Section 7(a) of the Securities Act of 1933 (15 U.S.C. 77g(a)), it provides audited financial statements for two years in a Securities Act registration statement for the initial public offering of the emerging growth company’s common equity securities.

\* \* \* \* \*

■ 7. Amend § 229.401 by removing Instruction 3 to paragraph (b) of Item 401 and adding an Instruction to Item 401 to the end of the section.

The addition reads as follows:

**§ 229.401 (Item 401) Directors, executive officers, promoters and control persons.**

\* \* \* \* \*

*Instruction to Item 401.* The information regarding executive officers called for by this Item need not be furnished in proxy or information statements prepared in accordance with Schedule 14A or Schedule 14C under the Exchange Act (§ 240.14a–101 and § 240.14c–101 of this chapter) if you are relying on General Instruction G of Form 10–K under the Exchange Act (§ 249.310 of this chapter), such information is furnished in a separate section captioned “Information about our Executive Officers,” and is included in Part I of your annual report on Form 10–K.

■ 8. Revise § 229.405 to read as follows:

**§ 229.405 (Item 405) Compliance with Section 16(a) of the Exchange Act.**

(a) *Reporting obligation.* Every registrant having a class of equity securities registered pursuant to Section 12 of the Exchange Act (15 U.S.C. 78l) and every closed-end investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) must:

(1) Under the caption “Delinquent Section 16(a) Reports,” identify each person who, at any time during the fiscal year, was a director, officer, beneficial owner of more than ten percent of any class of equity securities of the registrant registered pursuant to

Section 12 of the Exchange Act, or any other person subject to Section 16 of the Exchange Act with respect to the registrant because of the requirements of Section 30 of the Investment Company Act (“reporting person”) that failed to file on a timely basis reports required by Section 16(a) of the Exchange Act during the most recent fiscal year or prior fiscal years.

(2) For each such person, set forth the number of late reports, the number of transactions that were not reported on a timely basis, and any known failure to file a required form. A known failure to file would include, but not be limited to, a failure to file a Form 3, which is required of all reporting persons, and a failure to file a Form 5 in the absence of the written representation referred to in paragraph (b)(3) of this section, unless the registrant otherwise knows that no Form 5 is required.

*Instruction 1 to paragraph (a) of Item 405.* If no disclosure is required, registrants are encouraged to exclude the caption “Delinquent Section 16(a) Reports.”

*Instruction 2 to paragraph (a) of Item 405.* The registrant is only required to disclose a failure to file timely once. For example, if in the most recently concluded fiscal year a reporting person filed a Form 4 disclosing a transaction that took place in the prior fiscal year, and should have been reported in that year, the registrant should disclose that late filing and transaction pursuant to this Item 405 with respect to the most recently concluded fiscal year, but not in material filed with respect to subsequent years.

(b) *Scope of the Inquiry.* In determining whether disclosure is required pursuant to paragraph (a) of this section, the registrant may rely only on the following:

(1) A review of Forms 3 and 4 (17 CFR 249.103 and 249.104) and amendments thereto filed electronically with the Commission during the registrant’s most recent fiscal year;

(2) A review of Forms 5 (17 CFR 249.105) and amendments thereto filed electronically with the Commission with respect to the registrant’s most recent fiscal year; and

(3) Any written representation from the reporting person that no Form 5 is required. The registrant must maintain the representation in its records for two years, making a copy available to the Commission or its staff upon request.

■ 9. Amend § 229.407 by revising paragraphs (d)(3)(i)(B) and (g) to read as follows:

§ 229.407 (Item 407) Corporate governance.

\* \* \* \* \*

- (d) \* \* \*
(3)(i) \* \* \*

(B) The audit committee has discussed with the independent auditors the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board ("PCAOB") and the Commission;

\* \* \* \* \*

(g) Smaller reporting companies and emerging growth companies. (1) A registrant that qualifies as a "smaller reporting company," as defined by § 229.10(f)(1), is not required to provide:

(i) The disclosure required in paragraph (d)(5) of this Item in its first annual report filed pursuant to Section 13(a) or 15(d) of the Exchange Act (15 U.S.C. 78m(a) or 78o(d)) following the effective date of its first registration statement filed under the Securities Act (15 U.S.C. 77a et seq.) or Exchange Act (15 U.S.C. 78a et seq.); and

(ii) The disclosure required by paragraphs (e)(4) and (e)(5) of this Item.

(2) A registrant that qualifies as an "emerging growth company," as defined in Rule 405 of the Securities Act (§ 230.405 of this chapter) or Rule 12b-2 of the Exchange Act (§ 240.12b-2 of this chapter), is not required to provide the disclosure required by paragraph (e)(5) of this Item.

\* \* \* \* \*

- 10. Amend § 229.501 by:
■ a. Revising "Instruction to paragraph 501(b)(1)", Instruction 2 under "Instructions to paragraph 501(b)(3)", and paragraphs (b)(4) and (10); and
■ b. Removing paragraph (b)(11).

The revisions read as follows:

§ 229.501 (Item 501) Forepart of Registration Statement and Outside Front Cover Page of Prospectus.

\* \* \* \* \*

- (b) \* \* \*
(1) \* \* \*

Instruction to paragraph 501(b)(1): If your name is the same as that of a company that is well known, include information to eliminate any possible confusion with the other company. If your name indicates a line of business in which you are not engaged or in which you are engaged only to a limited extent, include information to eliminate any misleading inference as to your business.

\* \* \* \* \*

Instructions to paragraph 501(b)(3):

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

2. If it is impracticable to state the price to the public, explain the method

by which the price is to be determined. Instead of explaining the method on the outside front cover page of the prospectus, you may state that the offering price will be determined by a particular method or formula that is described in the prospectus and include a cross-reference to the location of such disclosure in the prospectus, including the page number. Highlight the cross-reference by prominent type or in another manner. If the securities are to be offered at the market price, or if the offering price is to be determined by a formula related to the market price, indicate the market and market price of the securities as of the latest practicable date.

\* \* \* \* \*

(4) Market for the securities. The national securities exchange(s) where the securities being offered are listed. If the securities being offered are not listed on a national securities exchange, the principal United States market(s) where the registrant, through the engagement of a registered broker-dealer, has actively sought and achieved quotation. In each case, also disclose the corresponding trading symbol(s) for the securities on such market(s).

\* \* \* \* \*

(10) Prospectus "Subject to Completion" legend. (i) If you use the prospectus before the effective date of the registration statement or if you use Rule 430A [§ 230.430A of this chapter] to omit pricing information and the prospectus is used before you determine the public offering price, include a prominent statement that:

(A) The information in the prospectus will be amended or completed;

(B) A registration statement relating to these securities has been filed with the Securities and Exchange Commission;

(C) The securities may not be sold until the registration statement becomes effective; and

(D) The prospectus is not an offer to sell the securities, and it is not soliciting an offer to buy the securities, in any state where offers or sales are not permitted.

(ii) The legend called for by paragraph (b)(10)(i) of this Item may be in the following or other clear, plain language:

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

(iii) Registrants may exclude the statement in paragraph (b)(10)(i)(D) of

this Item if the offering is not prohibited by state law.

\* \* \* \* \*

§ 229.502 [Amended]

- 11. Amend § 229.502 in paragraph (a) by removing the phrase "Item 503 of this Regulation S-K (17 CFR 229.503)" and adding in its place "Item 105 of this Regulation S-K (17 CFR 229.105)".

§ 229.503 [Amended]

- 12. Amend § 229.503 by removing "and risk factors" from the section heading and removing and reserving paragraph (c).

§ 229.512 [Amended]

- 13. Amend § 229.512 by removing and reserving paragraphs (c), (d), (e), and (f).

■ 14. Amend § 229.601:

- a. By revising paragraph (a)(1);
■ b. By adding paragraphs (a)(5) and (6);
■ c. By revising entry (4) to the exhibit table in paragraph (a);
■ d. By adding entry (104) to the exhibit table in paragraph (a);
■ e. By revising paragraph (b)(2);
■ f. By adding paragraph (b)(4)(vi);
■ g. By revising paragraph (b)(10)(i);
■ h. By adding paragraph (b)(10)(iv);
■ i. By revising the instructions to paragraph (b)(10);
■ j. By revising paragraphs (b)(13) and (b)(99); and
■ k. By adding paragraph (b)(104).

The revisions and additions read as follows:

§ 229.601 (Item 601) Exhibits.

(a) Exhibits and index required. (1) Subject to Rule 411(c) (§ 230.411(c) of this chapter) under the Securities Act and Rule 12b-23(c) (§ 240.12b-23(c) of this chapter) under the Exchange Act regarding incorporation of exhibits by reference, the exhibits required in the exhibit table must be filed as indicated, as part of the registration statement or report.

\* \* \* \* \*

(5) Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any

omitted schedule to the Commission or its staff upon request.

(6) The registrant may redact information from exhibits required to be filed by this Item if disclosure of such

information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses, and similar information).

**Exhibit Table**

\* \* \* \* \*

EXHIBIT TABLE

	*	*	*	*	*	*	*	*	*	*	*	*	*
(4) Instruments defining the rights of securities holders, including indentures, (i) through (v) .....	X	X	X	X	X	X	X	X	X	X	X	X	X
(vi) Description of registrant's securities .....													X
(104) Cover Page Interactive Data File .....									X			X	X

(b) \* \* \*  
(2) *Plan of acquisition, reorganization, arrangement, liquidation, or succession.*

(i) Any material plan of acquisition, disposition, reorganization, readjustment, succession, liquidation, or arrangement and any amendments thereto described in the statement or report.

(ii) The registrant may redact provisions or terms of exhibits required to be filed by paragraph (b)(2) of this Item if those provisions or terms are both not material and would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit. If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality

and competitive harm analyses. The registrant may request confidential treatment of the supplemental material submitted under paragraph (b)(2)(ii) of this Item pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 or 12b-4 (§ 230.418 or 240.12b-4 of this chapter).

\* \* \* \* \*

(4) \* \* \*  
(vi) For each class of securities that is registered under Section 12 of the Exchange Act, provide the information required by Item 202(a) through (d) and (f) of Regulation S-K (§ 229.202 of this chapter).

*Instruction 1 to paragraph (b)(4)(vi).* A registrant is only required to provide the information called for by Item 601(b)(4)(vi) if it is filing an annual report under Exchange Act Section 13(a) or 15(d).

*Instruction 2 to paragraph (b)(4)(vi).* For purposes of Item 601(b)(4)(vi), all references in Item 202 to securities to be or being registered, offered, or sold will mean securities that are registered as of the end of the period covered by the report with which the exhibit is filed. In addition, for purposes of this Item, the disclosure will be required for classes of securities that have not been retired by the end of the period covered by the report.

*Instruction 3 to paragraph (b)(4)(vi).* The registrant may incorporate by reference to an exhibit previously filed

in satisfaction of Item 601(b)(4)(vi) of Regulation S-K, as applicable, so long as there has not been any change to the information called for by Item 202 (§ 229.202 of this chapter) since the filing date of the linked filing. Such hyperlink will be deemed to satisfy the requirements of Item 601(b)(4)(vi) for the current filing.

\* \* \* \* \*

(10) *Material contracts.* (i)(A) Every contract not made in the ordinary course of business that is material to the registrant and is to be performed in whole or in part at or after the filing of the registration statement or report. In addition, for newly reporting registrants, every contract not made in the ordinary course of business that is material to the registrant and that was entered into not more than two years before the date on which such registrant:

(1) First files a registration statement or report; or

(2) Completes a transaction that had the effect of causing it to cease being a public shell company.

(B) The only contracts that need to be filed are those to which the registrant or a subsidiary of the registrant is a party or has succeeded to a party by assumption or assignment or in which the registrant or such subsidiary has a beneficial interest.

\* \* \* \* \*

(iv) The registrant may redact provisions or terms of exhibits required to be filed by this paragraph (b)(10) if those provisions or terms are both not material and would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit

or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit. If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission or its staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material submitted under this paragraph (b)(10)(iv) pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant if the registrant complies with the procedures outlined in Rules 418 or 12b-4 (§ 230.418 or § 240.12b-4 of this chapter).

*Instruction 1 to paragraph (b)(10) of Item 601:* For purposes of paragraph (b)(10)(i) of this Item, a "newly reporting registrant" is:

1. Any registrant filing a registration statement that, at the time of such filing, is not subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act, whether or not such registrant has ever previously been subject to the reporting requirements of Section 13(a) or 15(d),

2. Any registrant that has not filed an annual report since the revival of a previously suspended reporting obligation, and

3. Any registrant that:

a. Was a shell company, other than a business combination related shell company, as defined in Rule 12b-2 under the Exchange Act (17 CFR 240.12b-2), immediately before completing a transaction that has the effect of causing it to cease being a shell company and

b. Has not filed a registration statement or Form 8-K as required by

Items 2.01 and 5.06 of that form, since the completion of such transaction.

4. For example, newly reporting registrants would include a registrant that is filing its first registration statement under the Securities Act or the Exchange Act, and a registrant that was a public shell company, other than a business combination related shell company, and completes a reverse merger transaction causing it to cease being a shell company.

*Instruction 2 to paragraph (b)(10):* With the exception of management contracts, in order to comply with paragraph (b)(10)(iii) of this section, registrants need only file copies of the various compensatory plans and need not file each individual director's or executive officer's personal agreement under the plans unless there are particular provisions in such personal agreements whose disclosure in an exhibit is necessary to an investor's understanding of that individual's compensation under the plan.

*Instruction 3 to paragraph (b)(10):* If a material contract is executed or becomes effective during the reporting period reflected by a Form 10-Q or Form 10-K, it must be filed as an exhibit to the Form 10-Q or Form 10-K filed for the corresponding period. See paragraph (a)(4) of this Item. With respect to quarterly reports on Form 10-Q, only those contracts executed or becoming effective during the most recent period reflected in the report must be filed.

(13) *Annual or quarterly report to security holders.* (i) The registrant's annual report to security holders for its last fiscal year or its quarterly report to security holders, if all or a portion thereof is incorporated by reference in the filing. Such report, except for those portions thereof that are expressly incorporated by reference in the filing, is to be furnished for the information of the Commission and is not to be deemed "filed" as part of the filing. If the financial statements in the report have been incorporated by reference in the filing, the accountant's certificate must be manually signed in one copy. See Rule 439 (§ 230.439 of this chapter).

(ii) *Electronic filings.* If all, or any portion, of the annual or quarterly report to security holders is incorporated by reference into any electronic filing, all, or such portion of the annual or quarterly report to security holders so incorporated, must be filed in electronic format as an exhibit to the filing.

(99) *Additional exhibits.* (i) Any additional exhibits that the registrant may wish to file must be so marked as to indicate clearly the subject matters to which they refer.

(ii) If pursuant to Section 11(a) of the Securities Act (15 U.S.C. 77k(a)) an issuer makes generally available to its security holders an earnings statement covering a period of at least 12 months beginning after the effective date of the registration statement, and if such earnings statement is made available by "other methods" than those specified in paragraphs (a) or (b) of § 230.158 of this chapter, it must be filed as an exhibit to the Form 10-Q or the Form 10-K, as appropriate, covering the period in which the earnings statement was released.

\* \* \* \* \*

(104) *Cover Page Interactive Data File.* A Cover Page Interactive Data File (as defined in § 232.11 of this chapter) as required by Rule 406 of Regulation S-T (17 CFR 232.406), and in the manner provided by the EDGAR Filer Manual.

\* \* \* \* \*

■ 15. Amend § 229.1016 by adding "Instructions to Item 1016" at the end of the section to read as follows:

**§ 229.1016 (Item 1016) Exhibits.**

\* \* \* \* \*

Instructions to Item 1016:

1. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

2. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

■ 16. Amend § 229.1100 by:

■ a. Removing the designation "Instructions to Item 1100(c)(1)";

\* \* \* \* \*

■ b. Redesignating instruction 1 as “Instruction 1 to Item 1100(c)(1)” and revising it; and

■ c. Redesignating instructions 2 through 5 “Instruction 2 to paragraph (c)(1) of Item 1100.”, “Instruction 3 to paragraph (c)(1) of Item 1100.”, “Instruction 4 to paragraph (c)(1) of Item 1100.”, and “Instruction 5 to paragraph (c)(1) of Item 1100”, respectively.

The revision reads as follows:

**§ 229.1100 (Item 1100) General.**

\* \* \* \* \*

*Instruction 1 to paragraph (c)(1) of Item 1100.* In addition to the conditions in this paragraph (c)(1), any information incorporated by reference must comply with all applicable Commission rules pertaining to incorporation by reference, such as Rule 303 of Regulation S–T (§ 232.303 of this chapter), Rule 411 of Regulation C (§ 230.411 of this chapter), and Rule 12b-23 of Regulation 12B (§ 240.12b-23 of this chapter), except that for purposes of this paragraph (c)(1), an asset-backed issuer may incorporate by reference to a second document that incorporates pertinent information by reference to a third document.

\* \* \* \* \*

**§ 229.1103 [Amended]**

■ 17. Amend § 229.1103 in paragraph (b) by removing the phrase “Item 503(c) of Regulation S–K (§ 229.503(c))” and adding in its place “Item 105 of Regulation S–K (17 CFR 229.105)”.

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

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

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

\* \* \* \* \*

■ 19. Amend § 230.405 by adding in alphabetical order a definition for *Sub-underwriter* to read as follows:

**§ 230.405 Definition of terms.**

\* \* \* \* \*

*Sub-underwriter.* The term *sub-underwriter* means a dealer that is participating as an underwriter in an offering by committing to purchase securities from a principal underwriter for the securities but is not itself in privity of contract with the issuer of the securities.

\* \* \* \* \*

■ 20. Revise § 230.411 to read as follows:

**§ 230.411 Incorporation by reference.**

(a) *Prospectus.* Except as provided by this section, Item 1100(c) of Regulation AB (§ 229.1100(c) of this chapter) for registered offerings of asset-backed securities, or unless otherwise provided in the appropriate form, information must not be incorporated by reference into the prospectus. Where a summary or outline of the provisions of any document is required in the prospectus, the summary or outline may incorporate by reference particular items, sections or paragraphs of any exhibit and may be qualified in its entirety by such reference. In any financial statements, incorporating by reference, or cross-referencing to, information outside of the financial statements is not permitted unless otherwise specifically permitted or required by the Commission’s rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.

(b) *Information not required in a prospectus.* Information may be incorporated by reference in answer, or partial answer, to any item of a registration statement that calls for information not required to be included in a prospectus. Except as provided in the Commission’s rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable, financial information required to be given in comparative form for two or more fiscal years or periods must not be incorporated by reference unless the information incorporated by reference includes the entire period for which the comparative data is given. In any financial statements, incorporating by reference, or cross-referencing to, information outside of the financial statements is not permitted unless otherwise specifically permitted or required by the Commission’s rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.

(c) *Exhibits.* Any document or part thereof filed with the Commission pursuant to any Act administered by the Commission may be incorporated by reference as an exhibit to any registration statement filed with the Commission by the same or any other person. If any modification has occurred

in the text of any document incorporated by reference since the filing thereof, the registrant must file with the reference a statement containing the text of such modification and the date thereof.

(d) *Hyperlinks.* Include an active hyperlink to information incorporated into a registration statement or prospectus by reference if such information is publicly available on the Commission’s Electronic Data Gathering, Analysis and Retrieval System (“EDGAR”) at the time the registration statement or prospectus is filed. For hyperlinking to exhibits, please refer to Item 601 of Regulation S–K (§ 229.601 of this chapter) or the appropriate form.

(e) *General.* Include an express statement clearly describing the specific location of the information you are incorporating by reference. The statement must identify the document where the information was originally filed or submitted and the location of the information within that document. The statement must be made at the particular place where the information is required, if applicable. Information must not be incorporated by reference in any case where such incorporation would render the disclosure incomplete, unclear, or confusing. For example, unless expressly permitted or required, disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document.

■ 21. Revise § 230.491 to read as follows:

**§ 230.491 Information to be furnished under paragraph (6) of Schedule B.**

Any foreign government filing a registration statement pursuant to Schedule B of the act need state, in furnishing the information required by paragraph (6), the names and addresses only of principal underwriters, namely, underwriters in privity of contract with the registrant, provided they are designated as principal underwriters and a brief statement is made as to the discounts and commissions to be received by sub-underwriters or dealers.

**PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS**

■ 22. The authority citation for part 232 continues to read in part as follows:

**Authority:** 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z-3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a-6(c), 80a-8, 80a-29,

80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

\* \* \* \* \*

■ 23. Amend § 232.11 by adding in alphabetical order a definition for *Cover Page Interactive Data File* to read as follows:

**§ 232.11 Definitions of terms used in part 232.**

\* \* \* \* \*

*Cover Page Interactive Data File.* The term *Cover Page Interactive Data File* means the machine-readable computer code that presents in Inline XBRL electronic format the cover page information for specified forms as required by Rule 406 (§ 232.406 of this chapter). NOTE to definition of Cover Page Interactive Data File: When a filing is submitted using Inline XBRL, if permitted or required and as provided by the EDGAR Filer Manual, a portion of the Cover Page Interactive Data File must be embedded into a form with the remainder submitted as an exhibit to the form.

\* \* \* \* \*

■ 24. Amend § 232.102 by revising the second sentence of paragraph (a) introductory text and the third sentence of paragraph (d) to read as follows:

**§ 232.102 Exhibits.**

(a) \* \* \* Previously filed exhibits, whether in paper or electronic format, may be incorporated by reference into an electronic filing to the extent permitted by Rule 411 under the Securities Act (§ 230.411 of this chapter), Rule 12b–23 under the Exchange Act (§ 240.12b–23 of this chapter), Rule 0–4 under the Investment Company Act (§ 270.0–4 of this chapter) or Rule 303 of Regulation S–T (§ 232.303). \* \* \*

\* \* \* \* \*

(d) \* \* \* For electronic filings on Form S–6 (§ 239.16 of this chapter), Form N–14 (§ 239.23 of this chapter), Form F–10 (§ 239.40 of this chapter), Form 20–F (§ 249.220f of this chapter), Form 8–K (§ 249.308 of this chapter), Form N–5 (§ 274.5 of this chapter), Form N–1A (§ 274.11A of this chapter), Form N–2 (§ 274.11a–1 of this chapter), Form N–3 (§ 274.11b of this chapter), Form N–4 (§ 274.11c of this chapter), Form N–6 (§ 274.11d of this chapter), Form N–8B2 (§ 274.12 of this chapter), Form N–CSR (§ 274.128 of this chapter), or filings subject to Item 601 of Regulation S–K (§ 229.601 of this chapter), each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language or an exhibit that is filed with Form ABS–EE (§ 249.1401 of this chapter)) must

include an active link to an exhibit that is filed with the document or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. \* \* \*

\* \* \* \* \*

■ 25. Amend § 232.105 by revising paragraph (d) and adding paragraph (e) to read as follows:

**§ 232.105 Use of HTML and hyperlinks.**

\* \* \* \* \*

(d) Electronic filers submitting Form S–6 (§ 239.16 of this chapter), Form N–14 (§ 239.23 of this chapter), Form F–10 (§ 239.40 of this chapter), Form 20–F (§ 249.220f of this chapter), Form N–5 (§ 274.5 of this chapter), Form N–1A (§ 274.11A of this chapter), Form N–2 (§ 274.11a–1 of this chapter), Form N–3 (§ 274.11b of this chapter), Form N–4 (§ 274.11c of this chapter), Form N–6 (§ 274.11d of this chapter), Form N–8B2 (§ 274.12 of this chapter), Form N–CSR (§ 274.128 of this chapter), or a registration statement or report subject to Item 601 of Regulation S–K (§ 229.601 of this chapter), must submit such registration statement or report in HTML and each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language or an exhibit filed with Form ABS–EE (§ 249.1401 of this chapter)) must include an active link to an exhibit that is filed with the registration statement or report or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR, unless such exhibit is filed in paper pursuant to a temporary or continuing hardship exemption under Rules 201 or 202 of Regulation S–T (§ 232.201 or § 232.202) or pursuant to Rule 311 of Regulation S–T (§ 232.311).

*Instructions to paragraph (d):* (1) No hyperlink is required for any exhibit incorporated by reference that has not been filed with the Commission in electronic format.

(2) An electronic filer must correct an inaccurate or nonfunctioning link or hyperlink to an exhibit, in the case of a registration statement that is not yet effective, by filing an amendment to the registration statement containing the inaccurate or nonfunctioning link or hyperlink; or, in the case of a registration statement that has become effective or an Exchange Act report, an electronic filer must correct the inaccurate or nonfunctioning link or hyperlink in the next Exchange Act periodic report that requires, or includes, an exhibit pursuant to Item 601 of Regulation S–K (§ 229.601 of this chapter), in the case of an investment company, a report on Form N–CSR

(§ 274.128 of this chapter), or, in the case of a foreign private issuer (as defined in § 229.405 of this chapter), Form 20–F (§ 249.220f of this chapter) or Form F–10 (§ 239.40 of this chapter). Alternatively, an electronic filer may correct an inaccurate or nonfunctioning link or hyperlink in a registration statement that has become effective by filing a post-effective amendment to the registration statement.

(e) Except for exhibits, which are covered by paragraph (d) of this section, electronic filers that are incorporating information by reference pursuant to Rule 411 under the Securities Act (§ 230.411 of this chapter), Rule 12b–23 under the Exchange Act (§ 240.12b–23 of this chapter), or Rule 0–4 under the Investment Company Act (§ 270.0–4 of this chapter) must submit such registration statement or report in HTML and must include an active hyperlink to such incorporated information when required by those rules. A hyperlink is not required if the incorporated information is filed in paper pursuant to a temporary or continuing hardship exemption under Rules 201 or 202 of Regulation S–T (§ 232.201 or § 232.202) or pursuant to Rule 311 of Regulation S–T (§ 232.311).

*Instructions to paragraph (e):* (1) No hyperlink is required for any information incorporated by reference that has not been filed with the Commission in electronic format.

(2) In the case of a registration statement that is not yet effective, an electronic filer must correct an inaccurate or nonfunctioning hyperlink by filing an amendment to such registration statement.

■ 26. Amend § 232.303 by revising the first sentence of paragraph (b) to read as follows:

**§ 232.303 Incorporation by reference.**

\* \* \* \* \*

(b) If a filer incorporates by reference into an electronic filing any portion of an annual or quarterly report to security holders, it must also file the portion of the annual or quarterly report to security holders in electronic format as an exhibit to the filing, as required by Regulation S–K Item 601(b)(13) (§ 229.601(b)(13) of this chapter). \* \* \*

**§ 232.312 [Removed and Reserved]**

■ 27. Remove and reserve § 232.312.

■ 28. Add § 232.406 to read as follows:

**§ 232.406 Cover Page XBRL Data Tagging.**

Electronic filers submitting Forms 10–K (§ 249.310 of this chapter), 10–Q (§ 249.308a of this chapter), 8–K (§ 249.308 of this chapter), 20–F (§ 249.220f of this chapter) or 40–F

(§ 249.240f of this chapter) who are required to submit Interactive Data Files (§ 232.11) in Inline XBRL format in accordance with this Regulation S-T must tag in Inline XBRL electronic format, in the manner provided by the EDGAR Filer Manual, all of the information provided by the electronic filer that is required on the cover page of these forms.

**PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933**

■ 29. The authority citation for part 239 continues to read in part as follows:

**Authority:** 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z-2, 77z-3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78o-7 note, 78u-5, 78w(a), 78ll, 78mm, 80a-2(a), 80a-3, 80a-8, 80a-9, 80a-10, 80a-13, 80a-24, 80a-26, 80a-29, 80a-30, and 80a-37; and sec. 107, Pub. L. 112-106, 126 Stat. 312, unless otherwise noted.

\* \* \* \* \*

■ 30. Amend Form S-1 (referenced in § 239.11) by revising the last sentence of Instruction V under “General Instructions”, the first paragraph of Instruction VII under “General Instructions”, and Item 3 to read as follows:

**Note:** The text of Form S-1 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION**

Washington, DC 20549

**FORM S-1**

**REGISTRATION STATEMENT UNDER  
THE SECURITIES ACT OF 1933**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**V. Registration of Additional Securities**

\* \* \* See Rule 439(b) under the Securities Act (17 CFR 230.439(b)).

\* \* \* \* \*

**VII. Eligibility To Use Incorporation by Reference**

If a registrant meets the following requirements in paragraphs A-F immediately prior to the time of filing a registration statement on this Form, it may elect to provide information required by Items 3 through 11 of this Form in accordance with Item 11A and Item 12 of this Form. Notwithstanding the foregoing, in the financial statements, incorporating by reference or cross-referencing to information outside of the financial statements is not

permitted unless otherwise specifically permitted or required by the Commission’s rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable. \* \* \*

\* \* \* \* \*

**Item 3. Summary Information, Risk Factors and Ratio of Earnings to Fixed Charges.**

Furnish the information required by Items 105 and 503 of Regulation S-K (§ 229.105 and § 229.503 of this chapter).

\* \* \* \* \*

■ 31. Amend Form S-3 (referenced in § 239.13) by revising the last sentence of Instruction IV.A. under “General Instructions”, Item 3, and paragraph (d) of Item 12 to read as follows:

**Note:** The text of Form S-3 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION**

Washington, DC 20549

**FORM S-3**

**REGISTRATION STATEMENT UNDER  
THE SECURITIES ACT OF 1933**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**IV. Registration of Additional Securities and Additional Classes of Securities**

**A. Registration of Additional Securities Pursuant to Rule 462(b).**

\* \* \* See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

\* \* \* \* \*

**Item 3. Summary Information, Risk Factors and Ratio of Earnings to Fixed Charges.**

Furnish the information required by Items 105 and 503 of Regulation S-K (§ 229.105 and § 229.503 of this chapter).

\* \* \* \* \*

**Item 12. Incorporation of Certain Information by Reference.**

\* \* \* \* \*

(d) Any information required in the prospectus in response to Item 3 through Item 11 of this Form may be included in the prospectus through documents filed pursuant to Section 13(a), 14, or 15(d) of the Exchange Act

that are incorporated or deemed incorporated by reference into the prospectus that is part of the registration statement. Notwithstanding the foregoing, in the financial statements, incorporating by reference or cross-referencing to information outside of the financial statements is not permitted unless otherwise specifically permitted or required by the Commission’s rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.

\* \* \* \* \*

■ 32. Amend Form S-6 (referenced in § 239.16) by revising “Instructions as to Exhibits” to add a paragraph to read as follows:

**Note:** The text of Form S-6 does not, and this amendment will not, appear in the Code of Federal Regulations.

**Form S-6**

\* \* \* \* \*

**INSTRUCTIONS AS TO EXHIBITS**

\* \* \* \* \*

*Additional Instructions:* Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

2. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

3. The registrant may redact provisions or terms of exhibits required to be filed by paragraph (9) of section IX of Form N-8B-2 (Exhibits) if those provisions or terms are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit

or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

4. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 33. Amend Form S-11 (referenced in § 239.18) by revising the last sentence of Instruction G. under "General Instructions", the first paragraph of instruction H. under "General Instructions", and Item 3(a) to read as follows:

**Note:** The text of Form S-11 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION**

**Washington, DC 20549**

**FORM S-11**

FOR REGISTRATION UNDER THE  
SECURITIES ACT OF 1933 OF  
SECURITIES OF CERTAIN REAL  
ESTATE COMPANIES

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**G. Registration of Additional Securities**

\* \* \* Any opinion or consent required in the Rule 462(b) registration statement may be incorporated by reference from the earlier registration statement with respect to the offering, if: (i) Such opinion or consent expressly provides for such incorporation; and (ii) such opinion relates to the securities registered pursuant to Rule 462(b). See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

**H. Eligibility To Use Incorporation by Reference**

If a registrant meets the following requirements in paragraphs 1-6 immediately prior to the time of filing a registration statement on this Form, it may elect to provide information required by Items 3 through 28 of this Form in accordance with Item 28A and Item 29 of this Form. Notwithstanding the foregoing, in the financial statements, incorporating by reference or cross-referencing to information outside of the financial statement is not permitted unless otherwise specifically permitted or required by the Commission's rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable. \* \* \*

\* \* \* \* \*

**Item 3. Summary Information, Risk Factors and Ratio of Earnings to Fixed Charges.**

(a) Furnish the information required by Items 105 and 503 of Regulation S-K (§ 229.105 and § 229.503 of this chapter).

\* \* \* \* \*

■ 34. Amend Form N-14 (referenced in § 239.23) by revising the third paragraph of General Instruction G; and revising the Instruction to Item 16 to add new paragraphs to read as follows:

**Note:** The text of Form N-14 does not, and this amendment will not, appear in the Code of Federal Regulations.

**Form N-14**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**G. Incorporation by Reference and Delivery of Prospectuses or Reports Filed With the Commission**

\* \* \* \* \*

All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 411 under the Securities Act [17 CFR 230.411] (general rules on incorporation by reference in a prospectus) and rule 303 of Regulation S-T [17 CFR 232.303] (specific requirements for electronically filed documents).

\* \* \* \* \*

**Item 16. Exhibits**

\* \* \* \* \*

**Instructions:**

1. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

2. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

3. The registrant may redact provisions or terms of exhibits required to be filed by paragraph (13) of this Item if those provisions or terms are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would

likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

4. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 35. Amend Form S-4 (referenced in § 239.25) by revising the last sentence of Instruction K. under "General Instructions" and the first sentence of Item 3 to read as follows:

**Note:** The text of Form S-4 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES**  
**SECURITIES AND EXCHANGE**  
**COMMISSION**  
**Washington, DC 20549**  
**FORM S-4**  
**REGISTRATION STATEMENT UNDER**  
**THE SECURITIES ACT OF 1933**  
 \* \* \* \* \*

**GENERAL INSTRUCTIONS**  
 \* \* \* \* \*

**K. Registration of Additional Securities.**

\* \* \* Any opinion or consent required in the Rule 462(b) registration statement may be incorporated by reference from the earlier registration statement with respect to the offering, if: (i) Such opinion or consent expressly provides for such incorporation; and (ii) such opinion relates to the securities registered pursuant to Rule 462(b). See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

\* \* \* \* \*

**Item 3. Risk Factors, Ratio of Earnings to Fixed Charges and Other Information.**

Provide in the forepart of the prospectus a summary containing the information required by Items 105 and 503 of Regulation S-K (§ 229.105 and § 229.503 of this chapter) and the following:

\* \* \* \* \*

■ 36. Amend Form F-1 (referenced in § 239.31) by revising the last sentence of Instruction V. under "General Instructions," the first paragraph of instruction VI. under "General Instructions," and Item 3 to read as follows:

**Note:** The text of Form F-1 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES**  
**SECURITIES AND EXCHANGE**  
**COMMISSION**  
**Washington, DC 20549**  
**FORM F-1**  
**REGISTRATION STATEMENT UNDER**  
**THE SECURITIES ACT OF 1933**  
 \* \* \* \* \*

**GENERAL INSTRUCTIONS**  
 \* \* \* \* \*

**V. Registration of Additional Securities**

\* \* \* See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

**VI. Eligibility To Use Incorporation by Reference**

If a registrant meets the following requirements immediately prior to the time of filing a registration statement on this Form, it may elect to provide information required by Item 3 and Item 4 of this Form in accordance with Item 4A and Item 5 of this Form. Notwithstanding the foregoing, in the financial statements, incorporating by reference or cross-referencing to information outside of the financial statements is not permitted unless otherwise specifically permitted or

required by the Commission's rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.

\* \* \* \* \*

**Item 3. Summary Information, Risk Factors and Ratio of Earnings to Fixed Charges.**

Furnish the information required by Items 105 and 503 of Regulation S-K (§ 229.105 and § 229.503 of this chapter).

\* \* \* \* \*

■ 37. Amend Form F-3 (referenced in § 239.33) by revising the last sentence of Instruction IV.A. under "General Instructions" and Item 3 to read as follows:

**Note:** The text of Form F-3 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES**  
**SECURITIES AND EXCHANGE**  
**COMMISSION**  
**Washington, DC 20549**  
**FORM F-3**  
**REGISTRATION STATEMENT UNDER**  
**THE SECURITIES ACT OF 1933**  
 \* \* \* \* \*

**GENERAL INSTRUCTIONS**  
 \* \* \* \* \*

**IV. Registration of Additional Securities and Additional Classes of Securities**

**A. Registration of Additional Securities Pursuant to Rule 462(b).** \* \* \*

See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

\* \* \* \* \*

**Item 3. Summary Information, Risk Factors and Ratio of Earnings to Fixed Charges.**

Furnish the information required by Items 105 and 503 of Regulation S-K (§ 229.105 and § 229.503 of this chapter).

\* \* \* \* \*

■ 38. Amend Form F-4 (referenced in 239.34) by revising the last sentence of Instruction H. under "General Instructions" and Item 3 to read as follows:

**Note:** The text of Form F-4 does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES
SECURITIES AND EXCHANGE
COMMISSION

Washington, DC 20549

FORM F-4

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

\* \* \* \* \*

H. \* \* \* See Rule 439(b) under the
Securities Act [17 CFR 230.439(b)].

\* \* \* \* \*

Item 3. Risk Factors, Ratio of Earnings
to Fixed Charges and Other
Information.

Provide in the forepart of the
prospectus a summary containing the
information required by Items 105 and
503 of Regulation S-K (§ 229.105 and
§ 229.503 of this chapter) and the
following:

\* \* \* \* \*

■ 39. Revise Item 3 of Form F-7
(referenced in § 239.37) to read as
follows:

Note: The text of Form F-7 does not, and
this amendment will not, appear in the Code
of Federal Regulations.

UNITED STATES
SECURITIES AND EXCHANGE
COMMISSION

Washington, DC 20549

FORM F-7

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

\* \* \* \* \*

PART I—INFORMATION REQUIRED
TO BE SENT TO SHAREHOLDERS

\* \* \* \* \*

Item 3. Incorporation of Certain
Information by Reference

Information called for by this Form,
including exhibits, may be incorporated
by reference at the Registrant's option
from documents that the Registrant has
filed previously with the Commission
pursuant to Section 13(a) or 15(d) of the
Exchange Act or submitted to the
Commission pursuant to Rule 12g3-2(b)
under the Exchange Act. For
information that you are incorporating
by reference, identify the document
where the information was originally
filed or submitted and the specific
location of the information within that
document. The statement must be made
at the particular place where the
information is required, if applicable.
Unless expressly permitted or required,
disclosure must not be incorporated by
reference from a second document if

that second document incorporates
information pertinent to such disclosure
by reference to a third document. If any
information is incorporated by reference
into the prospectus, the prospectus must
provide the name, address and
telephone number of an officer of the
Registrant from whom copies of such
information may be obtained upon
request without charge.

\* \* \* \* \*

■ 40. Revise Item 3 of Form F-8
(referenced in § 239.38) to read as
follows:

Note: The text of Form F-8 does not, and
this amendment will not, appear in the Code
of Federal Regulations.

UNITED STATES
SECURITIES AND EXCHANGE
COMMISSION

Washington, DC 20549

FORM F-8

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

\* \* \* \* \*

PART I—INFORMATION REQUIRED
TO BE DELIVERED TO OFFEREEES OR
PURCHASERS

\* \* \* \* \*

Item 3. Incorporation of Certain
Information by Reference

Information called for by this Form,
including exhibits, may be incorporated
by reference at the Registrant's option
from documents that the Registrant has
filed previously with the Commission
pursuant to Section 13(a) or 15(d) of the
Exchange Act or submitted to the
Commission pursuant to Rule 12g3-2(b)
under the Exchange Act. For
information that you are incorporating
by reference, identify the document
where the information was originally
filed or submitted and the specific
location of the information within that
document. The statement must be made
at the particular place where the
information is required, if applicable.
Unless expressly permitted or required,
disclosure must not be incorporated by
reference from a second document if
that second document incorporates
information pertinent to such disclosure
by reference to a third document. If any
information is incorporated by reference
into the prospectus, the prospectus must
provide the name, address, and
telephone number of an officer of the
Registrant from whom copies of such
information may be obtained upon
request without charge.

\* \* \* \* \*

■ 41. Revise Item 4 of Form F-10
(referenced in § 239.40) to read as
follows:

Note: The text of Form F-10 does not, and
this amendment will not, appear in the Code
of Federal Regulations.

UNITED STATES
SECURITIES AND EXCHANGE
COMMISSION

Washington, DC 20549

FORM F-10

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

\* \* \* \* \*

PART I—INFORMATION REQUIRED
TO BE DELIVERED TO OFFEREEES OR
PURCHASERS

\* \* \* \* \*

Item 4. Incorporation of Certain
Information by Reference

Information called for by this Form,
including exhibits, may be incorporated
by reference at the Registrant's option
from documents that the Registrant has
filed previously with the Commission
pursuant to Section 13(a) or 15(d) of the
Exchange Act or submitted to the
Commission pursuant to Rule 12g3-2(b)
under the Exchange Act. For
information that you are incorporating
by reference, identify the document
where the information was originally
filed or submitted and the specific
location of the information within that
document. The statement must be made
at the particular place where the
information is required, if applicable.
Unless expressly permitted or required,
disclosure must not be incorporated by
reference from a second document if
that second document incorporates
information pertinent to such disclosure
by reference to a third document. If any
information is incorporated by reference
into the prospectus, the prospectus must
provide the name, address, and
telephone number of an officer of the
Registrant from whom copies of such
information may be obtained upon
request without charge.

\* \* \* \* \*

■ 42. Revise Item 3 of Form F-80
(referenced in § 239.41) to read as
follows:

Note: The text of Form F-80 does not, and
this amendment will not, appear in the Code
of Federal Regulations.

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION**

Washington, DC 20549

**FORM F-80**

**REGISTRATION STATEMENT UNDER  
THE SECURITIES ACT OF 1933**

\* \* \* \* \*

**PART I—INFORMATION REQUIRED  
TO BE DELIVERED TO OFFEREEES OR  
PURCHASERS**

\* \* \* \* \*

**Item 3 Incorporation of Certain  
Information by Reference**

Information called for by this Form, including exhibits, may be incorporated by reference at the Registrant's option from documents that the Registrant has filed previously with the Commission pursuant to Section 13(a) or 15(d) of the Exchange Act or submitted to the Commission pursuant to Rule 12g3-2(b) under the Exchange Act. For information that you are incorporating by reference, identify the document where the information was originally filed or submitted and the specific location of the information within that document. The statement must be made at the particular place where the information is required, if applicable. Unless expressly permitted or required, disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document. If any information is incorporated by reference into the prospectus, the prospectus must provide the name, address, and telephone number of an officer of the Registrant from whom copies of such information may be obtained upon request without charge.

\* \* \* \* \*

■ 43. Amend Form SF-1 (referenced in § 239.44) by revising the last sentence of Instruction III. under "General Instructions" and the last sentence of Item 2 to read as follows:

**Note:** The text of Form SF-1 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION,**

Washington, DC 20549

**FORM SF-1**

**REGISTRATION STATEMENT UNDER  
THE SECURITIES ACT OF 1933**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**III. Registration of Additional  
Securities**

\* \* \* See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

\* \* \* \* \*

**Item 2. Inside Front and Outside Back  
Cover Pages of Prospectus.**

Furnish the information required by Items 105 and 503 of Regulation S-K (17 CFR 229.105 and 17 CFR 229.503) and Item 1103 of Regulation AB (17 CFR 229.1103).

\* \* \* \* \*

■ 44. Amend Form SF-3 (referenced in § 239.45) by revising the last sentence of Instruction III. under "General Instructions" and the last sentence of Item 2 to read as follows:

**Note:** The text of Form SF-3 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES  
SECURITIES AND EXCHANGE  
COMMISSION**

Washington, DC 20549

**FORM SF-3**

**REGISTRATION STATEMENT UNDER  
THE SECURITIES ACT OF 1933**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**III. Registration of Additional  
Securities Pursuant to Rule 462(b)**

\* \* \* See Rule 439(b) under the Securities Act [17 CFR 230.439(b)].

\* \* \* \* \*

**Item 2. Inside Front and Outside Back  
Cover Pages of Prospectus.**

Furnish the information required by Items 105 and 503 of Regulation S-K (17 CFR 229.105 and 17 CFR 229.503) and Item 1103 of Regulation AB (17 CFR 229.1103).

\* \* \* \* \*

**PART 240—GENERAL RULES AND  
REGULATIONS, SECURITIES  
EXCHANGE ACT OF 1934**

■ 45. The authority citation for part 240 continues to read in part as follows:

**Authority:** 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z-2, 77z-3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c-3, 78c-5, 78d, 78e, 78f, 78g, 78i, 78j, 78j-1, 78k, 78k-1, 78l, 78m, 78n, 78n-1, 78o, 78o-4, 78o-10, 78p, 78q, 78q-1, 78s, 78u-5, 78w, 78x, 78ll, 78mm, 80a-20, 80a-23, 80a-29, 80a-37, 80b-3, 80b-

4, 80b-11, 7201 *et seq.*; and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111-203, 939A, 124 Stat. 1887 (2010); sec. 503 and 602, and Pub. L. 112-106, 126 Stat. 326 (2012), unless otherwise noted.

\* \* \* \* \*

■ 46. Revise § 240.12b-23 to read as follows:

**§ 240.12b-23 Incorporation by reference.**

(a) *Registration statement or report.* Except as provided by this section or in the appropriate form, information may be incorporated by reference in answer, or partial answer, to any item of a registration statement or report.

(b) *Financial information.* Except as provided in the Commission's rules, financial information required to be given in comparative form for two or more fiscal years or periods must not be incorporated by reference unless the information incorporated by reference includes the entire period for which the comparative data is given. In the financial statements, incorporating by reference, or cross-referencing to, information outside of the financial statements is not permitted unless otherwise specifically permitted or required by the Commission's rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.

(c) *Exhibits.* Any document or part thereof filed with the Commission pursuant to any Act administered by the Commission may be incorporated by reference as an exhibit to any statement or report filed with the Commission by the same or any other person. Any document or part thereof filed with an exchange pursuant to the Act may be incorporated by reference as an exhibit to any statement or report filed with the exchange by the same or any other person. If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the registrant must file with the reference a statement containing the text of any such modification and the date thereof.

(d) *Hyperlinks.* You must include an active hyperlink to information incorporated into a registration statement or report by reference if such information is publicly available on the Commission's Electronic Data Gathering, Analysis and Retrieval System ("EDGAR") at the time the registration statement or form is filed. For hyperlinking to exhibits, please refer to Item 601 of Regulation S-K (§ 229.601 of this chapter) or the appropriate form.

(e) General. Include an express statement clearly describing the specific location of the information you are incorporating by reference. The statement must identify the document where the information was originally filed or submitted and the location of the information within that document. The statement must be made at the particular place where the information is required, if applicable. Information must not be incorporated by reference in any case where such incorporation would render the disclosure incomplete, unclear, or confusing. For example, unless expressly permitted or required, disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document.

§ 240.12b-32 [Removed and Reserved]

- 47. Remove and reserve § 240.12b-32.
■ 48. Amend § 240.14a-101 by revising the first sentence of Note D.1 to read as follows:

§ 240.14a-101 Schedule 14A. Information required in proxy statement.

\* \* \* \* \*

D. \* \* \*

1. Disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document. \* \* \*

\* \* \* \* \*

§ 240.16a-3 [Amended]

- 49. Amend § 240.16a-3 by removing and reserving paragraph (e).

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

- 50. The authority citation for part 249 continues to read in part as follows:

Authority: 15 U.S.C. 78a et seq. and 7201 et seq.; 12 U.S.C. 5461 et seq.; 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111-203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112-106, 126 Stat. 309 (2012); Sec. 107, Pub. L. 112-106, 126 Stat. 313 (2012), and Sec. 72001, Pub. L. 114-94, 129 Stat. 1312 (2015), unless otherwise noted.

\* \* \* \* \*

General Instruction 3 to Form 3 (referenced in § 249.103) [Amended]

- 51. Remove and reserve paragraph (c) of General Instruction 3 to Form 3 (referenced in § 249.103).

General Instruction 2 to Form 4 (referenced in § 249.104) [Amended]

- 52. Remove and reserve paragraph (c) of General Instruction 2 to Form 4 (referenced in § 249.104).

General Instruction 2 to Form 5 (referenced in § 249.105) [Amended]

- 53. Remove and reserve paragraph (c) of General Instruction 2 to Form 5 (referenced in § 249.105).

- 54. Amend Form 8-A (referenced in § 249.208a) by revising the Instructions as to Exhibits to read as follows:

Note: The text of Form 8-A does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-A

FOR REGISTRATION OF CERTAIN CLASSES OF SECURITIES PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

\* \* \* \* \*

INSTRUCTIONS FOR EXHIBITS

If the securities to be registered on this form are to be registered on an exchange on which other securities of the registrant are registered, or are to be registered pursuant to Section 12(g) of the Act, copies of all constituent instruments defining the rights of the holders of each class of such securities, including any contracts or other documents which limit or qualify the rights of such holders, must be filed as exhibits with each copy of the registration statement filed with the Commission or with an exchange, subject to Rule 12b-23(c) regarding incorporation of exhibits by reference.

\* \* \* \* \*

- 55. Amend Form 10 (referenced in § 249.210) by revising the first sentence in Item 1A to read as follows:

Note: The text of Form 10 does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES

Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

\* \* \* \* \*

INFORMATION REQUIRED IN REGISTRATION STATEMENT

\* \* \* \* \*

Item 1A. Risk Factors.

Set forth, under the caption "Risk Factors," where appropriate, the risk factors described in Item 105 of Regulation S-K (§ 229.105 of this chapter) applicable to the registrant.

\* \* \*

\* \* \* \* \*

- 56. Amend Form 20-F (referenced in § 249.220f) by:

- a. Adding a field to the cover page to include trading symbol(s);
■ b. Adding Instruction 6 under "Instructions to Item 5";
■ c. Revising Instruction 1(b) under "Instructions to Item 10";
■ d. Revising Instructions 1 and 2 under "Instructions to Item 12";
■ e. Revising the introductory text and Instruction 4(a) and adding Instructions 2(d) and 104 under "Instructions As To Exhibits".

The additions and revisions read as follows:

Note: The text of Form 20-F does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 20-F

\* \* \* \* \*

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Table with 3 columns: Title of each class, Trading symbol(s), Name of each exchange on which registered

\* \* \* \* \*

GENERAL INSTRUCTIONS

\* \* \* \* \*

Item 5. Operating and Financial Review and Prospects

\* \* \* \* \*

*Instructions to Item 5:*

\* \* \* \* \*

6. Generally, the discussion shall cover the periods covered by the financial statements and the registrant may use any format that in the registrant's judgment enhances a reader's understanding. For registrants providing financial statements covering three years in a filing, a discussion of the earliest of the three years may be omitted if such discussion was already included in any other of the registrant's prior filings on EGDAR that required disclosure in compliance with Item 5 of Form 20-F, provided that registrants electing not to include a discussion of the earliest year must include a statement that identifies the location in the prior filing where the omitted discussion may be found.

\* \* \* \* \*

**Item 10. Additional Information**

\* \* \* \* \*

*Instructions to Item 10:*

\* \* \* \* \*

## 1. \* \* \*

(b) If the information called for by Item 10.B has been reported previously in a registration statement on Form 20-F or a registration statement filed under the Securities Act and has not changed, you may incorporate that information by a specific reference in the annual report to the previous registration statement or, to the extent that this information has been provided in the exhibit required by instruction 2(d) of the Instructions as to Exhibits, you may refer to the exhibit for this information.

\* \* \* \* \*

**Item 12. Description of Securities Other Than Equity Securities**

\* \* \* \* \*

*Instructions to Item 12:*

\* \* \* \* \*

1. If you are using the form as an annual report, provide the information required by Item 12.D.3 and Item 12.D.4 under this Item of your annual report and provide the remainder of the information required by this Item in an exhibit to such report pursuant to paragraph 2(d) of Instructions as to Exhibits.

2. You do not need to include any information in a registration statement, prospectus, or annual report on Form 20-F in response to Item 305(a)(2) of the Trust Indenture Act of 1939, 15 U.S.C. 77aaa *et seq.*, as amended, if the information is not otherwise required by this Item or Instruction 2(d) under Instructions as to Exhibits of this Form.

**INSTRUCTIONS AS TO EXHIBITS**

File the exhibits listed below as part of an Exchange Act registration statement or report. Exchange Act Rule 12b-23(c) explains the circumstances in which you may incorporate exhibits by reference. Exchange Act Rule 24b-2 explains the procedure to be followed in requesting confidential treatment of information required to be filed.

Previously filed exhibits may be incorporated by reference. If any previously filed exhibits have been amended or modified, file copies of the amendment or modification or copies of the entire exhibit as amended or modified.

If the Form 20-F registration statement or annual report requires the inclusion, as an exhibit or attachment, of a document that is in a foreign language, you must provide instead either an English translation or an English summary of the foreign language document in accordance with Exchange Act Rule 12b-12(d) (17 CFR 240.12b-12(d)) for both electronic and paper filings. You may submit a copy of the unabridged foreign language document along with the English translation or summary as permitted by Regulation S-T Rule 306(b) (17 CFR 232.306(b)) for electronic filings or by Exchange Act Rule 12b-12(d)(4) (17 CFR 240.12b-12(d)(4)) for paper filings.

Include an exhibit index in each registration statement or report you file, immediately preceding the exhibits you are filing. The exhibit index must list each exhibit according to the number assigned to it below. If an exhibit is incorporated by reference, note that fact in the exhibit index. For paper filings, the pages of the manually signed original registration statement should be numbered in sequence, and the exhibit index should give the page number in the sequential numbering system where each exhibit can be found.

Schedules (or similar attachments) to the exhibits required by this Form 20-F are not required to be filed unless they contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

The registrant may redact information from exhibits required to be filed by this Form 20-F if disclosure of that information would constitute a clearly unwarranted invasion of personal privacy (*e.g.*, disclosure of bank account numbers, social security numbers, home addresses and similar information). The registrant is not required to undertake or provide to the Commission upon request a materiality or competitive harm analysis of this redacted information.

\* \* \* \* \*

## 2. \* \* \*

(d) If a registrant is filing an annual report under Exchange Act Section 13(a) or 15(d), the registrant must provide as an exhibit a description of the rights of each class of securities that is registered under Section 12 of the Exchange Act as of the end of the period covered by the report with which the exhibit is filed. The description must include information for the securities comparable to that required by Item 9.A.3, A.5, A.6, and A.7, Item 10.B.3, B.4, B.6, B.7, B.8, B.9, and B.10, and Item 12.A, 12.B, 12.C, and 12.D.1 and 12.D.2 of Form 20-F (collectively, the "Description of Securities"). However, for purposes of this paragraph 2(d), all references in those Items to securities to be or being registered, offered or sold will mean securities that are registered as of the end of the period covered by the report with which the exhibit is filed. In addition, for purposes of this Item, the disclosure will be required for classes of securities that have not been retired by the end of the period covered by the report. A registrant may incorporate by reference and provide an active hyperlink to a prior periodic filing containing the disclosure required by this paragraph 2(d) so long as there has not been any change to the information called for by the Description of Securities since the filing date of the linked filing. Such hyperlink will be deemed to satisfy the requirements of this paragraph 2(d) for the current filing.

\* \* \* \* \*

4.(a) Every contract not made in the ordinary course of business that is material to the registrant and is to be performed in whole or in part at or after the filing of the registration statement or report. In addition, for newly reporting registrants, every contract not made in the ordinary course of business that is material to the registrant and that was entered into not more than two years before the date on which such registrant:

(i) First files a registration statement or report; or

(ii) completes a transaction that had the effect of causing it to cease being a public shell company.

The only contracts that must be filed are those to which the registrant or a subsidiary of the registrant is a party or has succeeded to a party by assumption or assignment or in which the registrant or such subsidiary has a beneficial interest.

The registrant may redact provisions or terms of exhibits required to be filed by this Form 20-F if those provisions or terms are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit or exhibits to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request that the registrant provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the

Commission staff may request that registrant amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses.

The registrant may request confidential treatment of the supplemental material submitted to the Commission or the staff pursuant to Rule 83 (17 CFR 200.83) while it is in the possession of the Commission staff. After reviewing the supplemental information, the Commission staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 or 12b-4 (17 CFR 230.418 or 17 CFR 240.12b-4).

**Note:** A "newly reporting registrant" is (i) any registrant filing a registration statement that, at the time of such filing, is not subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act, whether or not such registrant has ever previously been subject to the reporting requirements of Section 13(a) or 15(d), (ii) any registrant that has not filed an annual report since the revival of a previously suspended reporting obligation, and (iii) any registrant that (a) was a shell company, other than a business combination related shell company, as defined in Rule 12b-2 under the Exchange Act (17 CFR 240.12b-2), immediately before completing a transaction that has the effect of causing it to cease being a shell company and (b) has not filed a Form 20-F since the completion of such transaction. For example, newly reporting registrants would include (i) a registrant that is filing its first registration statement under the Securities Act or the

Exchange Act, and (ii) a registrant that was a public shell company, other than a business combination related shell company, and completes a reverse merger transaction causing it to cease being a shell company.

\* \* \* \* \*

102 and 103 [Reserved]

104. *Cover Page Interactive Data File.* If the Form 20-F is being used as an annual report, a Cover Page Interactive Data File (as defined in 17 CFR 232.11) as required by Rule 406 of Regulation S-T [17 CFR 232.406], and in the manner provided by the EDGAR Filer Manual.

- 57. Amend Form 40-F (referenced in § 249.240f) by:
  - a. Adding a field to the cover page to include trading symbol(s);
  - b. Adding paragraph B.17 under "General Instructions"; and
  - c. Revising paragraph D.1 under "General Instructions".

The additions and revisions read as follows:

**Note:** The text of Form 40-F does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 40-F**

\* \* \* \* \*

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading symbol(s)	Name of each exchange on which registered

\* \* \* \* \*

*B. Information To Be Filed on This Form*

\* \* \* \* \*

(17) Cover Page Interactive Data File. If the Form 40-F is being used as an annual report, a Cover Page Interactive Data File (as defined in 17 CFR 232.11) as required by Rule 406 of Regulation S-T [17 CFR 232.406], in the manner provided by the EDGAR Filer Manual and listed as exhibit 104.

\* \* \* \* \*

*D. Application of General Rules and Regulations*

(1) Rules 12b-2, 12b-5, 12b-10, 12b-11, 12b-12, 12b-13, 12b-14, 12b-21, 12b-22, 12b-23(a), 12b-23(b), 12b-

23(d), 12b-25, 12b-33 and 12b-37 under the Exchange Act shall not apply to filings on this Form. The rules and regulations applicable in the home jurisdiction regarding the form and method of preparation of disclosure documents shall apply to filings on this Form. Exchange Act rules and regulations other than Rules 12b-2, 12b-5, 12b-10, 12b-11, 12b-12, 12b-13, 12b-14, 12b-21, 12b-22, 12b-23(a), 12b-23(d), 12b-23(b), 12b-25, 12b-33 and 12b-37 shall apply to filings on this Form unless specifically excluded in this Form. \* \* \*

\* \* \* \* \*

■ 58. Amend Form 8-K (referenced in § 249.308) by adding a field to the cover page for securities registered pursuant to

Section 12(b) of the Exchange Act, the title of each class of such securities, trading symbol(s) and name of each exchange on which registered; and adding Instructions 4, 5 and 6 under Item 1.01 to read as follows:

**Note:** The text of Form 8-K does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION,**

**Washington, DC 20549**

**FORM 8-K**

\* \* \* \* \*

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
---------------------	-------------------	---

\* \* \* \* \*

**Instructions**

\* \* \* \* \*

4. To the extent a material definitive agreement is filed as an exhibit under this Item 1.01, schedules (or similar attachments) to the exhibits are not required to be filed unless they contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

5. To the extent a material definitive agreement is filed as an exhibit under this Item 1.01, the registrant may redact information from the exhibit if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

6. To the extent a material definitive agreement is filed as an exhibit under this Item 1.01, the registrant may redact provisions or terms of the exhibit if those provisions or terms are both (i) not

material and (ii) would likely cause competitive harm to the registrant if publicly disclosed, provided that the registrant intends to incorporate by reference this filing into its future periodic reports or registration statements, as applicable, in satisfaction of Item 601(b)(10) of Regulation S-K. If it chooses to redact information pursuant to this instruction, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission or its staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses.

The registrant may request confidential treatment of the supplemental material submitted under Instruction 6 of this Item pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 or 12b-4 (§ 230.418 or 240.12b-4 of this chapter).

\* \* \* \* \*

■ 59. Amend Form 10-Q (referenced in § 249.308a) by adding a field to the cover page for securities registered pursuant to Section 12(b) of the Exchange Act, the title of each class of such securities, trading symbol(s) and name of each exchange on which registered:

**Note:** The text of Form 10-Q does not, and this amendment will not, appear in the Code of Federal Regulations

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

\* \* \* \* \*

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
---------------------	-------------------	---

\* \* \* \* \*

■ 60. Amend Form 10-K (referenced in § 249.310) by:

■ a. Revising the last sentence of Instruction (G)(3) under "General Instructions", the first sentence in Item 1A, and paragraph (a) under "Supplemental Information to be Furnished With Reports Filed Pursuant to Section 15(d) of the Act by Registrants Which Have Not Registered Securities Pursuant to Section 12 of the Act";

■ b. Removing the second sentence of Instruction (G)(4) under "General Instructions", the checkbox that relates

to disclosure under Item 405, and the instruction to Item 10; and

■ c. Adding a field to the cover page to include trading symbol(s).

The revision and addition read as follows:

**Note:** The text of Form 10-K does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 GENERAL INSTRUCTIONS**

\* \* \* \* \*

*G. Information To Be Incorporated by Reference*

\* \* \* \* \*

(3) \* \* \* See the Instruction to Item 401 of Regulation S-K (§ 229.401 of this chapter).

\* \* \* \* \*

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

\* \* \* \* \*

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered

\* \* \* \* \*

Item 1A. Risk Factors

Set forth, under the caption "Risk Factors," where appropriate, the risk factors described in Item 105 of Regulation S-K (§ 229.105 of this chapter) applicable to the registrant.

\* \* \* \* \*

\* \* \* \* \*

SUPPLEMENTAL INFORMATION TO BE FURNISHED WITH REPORTS FILED PURSUANT TO SECTION 15(d) OF THE ACT BY REGISTRANTS WHICH HAVE NOT REGISTERED SECURITIES PURSUANT TO SECTION 12 OF THE ACT

(a) Except to the extent that the materials enumerated in (1) and/or (2) below are specifically incorporated into this Form by reference, every registrant which files an annual report on this Form pursuant to Section 15(d) of the Act must furnish to the Commission for its information, at the time of filing its report on this Form, four copies of the following: \* \* \*

\* \* \* \* \*

■ 61. Amend Form 10-D (referenced in § 249.312 of this chapter) by:

■ a. Removing and reserving General Instruction D(2)(a); and

■ b. Revising General Instruction D(2)(d) to read as follows:

Note: The text of Form 10-D does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-D

ASSET-BACKED ISSUER DISTRIBUTION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 GENERAL INSTRUCTIONS

\* \* \* \* \*

(d) Exchange Act Rules 12b-23 (17 CFR 240.12b-23) (additional rules on incorporation by reference for reports

filed pursuant to Sections 13 and 15(d) of the Act).

\* \* \* \* \*

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1934

■ 62. The authority citation for part 270 continues to read in part as follows:

Authority: 15 U.S.C. 80a-1 et seq., 80a-34(d), 80a-37, 80a-39, and Pub. L. 111-203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

\* \* \* \* \*

■ 63. Revise § 270.0-4 to read as follows:

§ 270.0-4 Incorporation by reference.

(a) Registration statements and reports. Except as provided by this section or in the appropriate form, information may be incorporated by reference in answer, or partial answer, to any item of a registration statement or report. Where an item requires a summary or outline of the provisions of any document, the summary or outline may incorporate by reference particular items, sections, or paragraphs of any exhibit and may be qualified in its entirety by such reference.

(b) Financial information. Except as provided in the Commission's rules, financial information required to be given in comparative form for two or more fiscal years or periods must not be incorporated by reference unless the information incorporated by reference includes the entire period for which the comparative data is given. In the financial statements, incorporating by reference, or cross-referencing to, information outside of the financial statements is not permitted unless otherwise specifically permitted or required by the Commission's rules or by U.S. Generally Accepted Accounting Principles or International Financial Reporting Standards as issued by the International Accounting Standards Board, whichever is applicable.

(c) Exhibits. Any document or part thereof, including any financial statement or part thereof, filed with the Commission pursuant to any Act

administered by the Commission may be incorporated by reference as an exhibit to any registration statement, application, or report filed with the Commission by the same or any other person. If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the registrant must file with the reference a statement containing the text of any such modification and the date thereof.

(d) Hyperlinks. Include an active hyperlink to information incorporated into a registration statement, application, or report by reference if such information is publicly available on the Commission's Electronic Data Gathering, Analysis and Retrieval System ("EDGAR") at the time the registration statement, application, or report is filed. For hyperlinking to exhibits, please refer to the appropriate form.

(e) General. Include an express statement clearly describing the specific location of the information you are incorporating by reference. The statement must identify the document where the information was originally filed or submitted and the location of the information within that document. The statement must be made at the particular place where the information is required, if applicable. Information must not be incorporated by reference in any case where such incorporation would render the disclosure incomplete, unclear, or confusing. For example, unless expressly permitted or required, disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document.

§ 270.8b-23 [Removed and Reserved]

■ 64. Remove and reserve § 270.8b-23.

§ 270.8b-24 [Removed and Reserved]

■ 65. Remove and reserve § 270.8b-24.

§ 270.8b-32 [Removed and Reserved]

■ 66. Remove and reserve § 270.8b-32.

**PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1934**

■ 67. The authority citation for part 274 continues to read in part as follows:

**Authority:** 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78l, 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, 80a–29, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

\* \* \* \* \*

■ 68. Amend Form N–5 (referenced in §§ 239.24 and 274.5 of this chapter) “Instructions as to Exhibits” by adding paragraphs 1 through 4 immediately following the introductory text to read as follows:

**Note:** The text of Form N–5 does not, and this amendment will not, appear in the Code of Federal Regulations.

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM N–5**

**REGISTRATION STATEMENT SMALL BUSINESS INVESTMENT COMPANY UNDER THE SECURITIES ACT OF 1933 AND THE INVESTMENT COMPANY ACT OF 1940 \***

\* \* \* \* \*

**INSTRUCTIONS AS TO EXHIBITS**

\* \* \* \* \*

*Instructions:* Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

2. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

3. The registrant may redact provisions or terms of exhibits required to be filed by paragraph 9 of this Item if those provisions or terms are both (i) not material and (ii) would likely cause

competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant’s supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant’s materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

4. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 69. Amend Form N–1A (referenced in §§ 239.15A and 274.11A of this chapter) by revising General Instruction D.2 and the Instructions to Item 28 to read as follows:

**Note:** The text of Form N–1A does not, and this amendment will not, appear in the Code of Federal Regulations.

**FORM N–1A**

\* \* \* \* \*

**General Instructions**

\* \* \* \* \*

*D. Incorporation by Reference*

\* \* \* \* \*

2. General Requirements

All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 411 under the Securities Act [17 CFR 230.411] (general rules on incorporation by reference in a prospectus); rule 303 of Regulation S–T [17 CFR 232.303] (specific requirements for electronically filed documents); and rule 0–4 [17 CFR 270.0–4] (additional rules on incorporation by reference for Funds).

\* \* \* \* \*

**Item 28. Exhibits**

\* \* \* \* \*

**Instructions**

1. A Fund that is a Feeder Fund also must file a copy of all codes of ethics applicable to the Master Fund.

2. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

3. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

4. The registrant may redact provisions or terms of exhibits required to be filed by paragraph (h) of this Item if those provisions or terms are both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been

excluded from the exhibit because it is both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

5. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 70. Amend Form N-2 (referenced in §§ 239.14 and 274.11a-1 of this chapter) by revising General Instruction F and the Instructions to Item 25.2 to add Instructions 4, 5, 6, and 7 to read as follows:

**Note:** The text of Form N-2 does not, and this amendment will not, appear in the Code of Federal Regulations.

**FORM N-2**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

**F. Incorporation by Reference**

Incorporation by reference permits a Registrant to include documents and exhibits filed previously with the Commission as part of the registration

statement by making reference to where, and under what designation, these documents can be found in previous filings. A Registrant may incorporate all or part of the Statement of Additional Information (the "SAI") into the prospectus delivered to investors without physically delivering the SAI with the prospectus, so long as the SAI is available to investors upon request at no charge and any information or documents incorporated by reference into the SAI are provided along with the SAI, except to the extent provided by paragraph F.3 below.

In general, a Registrant may incorporate by reference, in response to any item of Form N-2 not required to be included in the prospectus, any information contained elsewhere in the registration statement or in other statements, applications, or reports filed with the Commission.

A Registrant may incorporate by reference into the prospectus or the SAI in response to Item 4.1 or 24 of this form the information contained in Form N-CSR [17 CFR 249.331 and 274.128] or any report to shareholders meeting the requirements of Section 30(e) of the 1940 Act [15 U.S.C. 80a-29(e)] and Rule 30e-1 [17 CFR 270.30e-1] thereunder (and a Registrant that has elected to be regulated as a business development company may so incorporate into Items 4.2, 8.6.c, or 24 of this form the information contained in its annual report under the Securities Exchange Act of 1934 [15 U.S.C. 78a *et seq.*] (the "Exchange Act")), provided:

1. The material incorporated by reference is prepared in accordance with, and covers the periods specified by, this form.

2. The Registrant states in the prospectus or the SAI, at the place where the information required by Items 4.1, 4.2, 8.6.c, or 24 of this form would normally appear, that the information is incorporated by reference from a report to shareholders or a report on Form N-CSR. (The Registrant also may describe briefly, in either the prospectus, the SAI, or Part C of the registration statement (in response to Item 25.1) those portions of the report to shareholders or report on Form N-CSR that are not incorporated by reference and are not a part of the registration statement.)

3. The material incorporated by reference is provided with the prospectus and/or the SAI to each person to whom the prospectus and/or the SAI is sent or given, unless the person holds securities of the Registrant and otherwise has received a copy of the material. (The Registrant must state in the prospectus and/or the SAI that it

will furnish, without charge, a copy of such material on request and provide the name, address, and telephone number of the person to contact.)

All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 411 under the Securities Act [17 CFR 230.411] (general rules on incorporation by reference in a prospectus); rule 303 of Regulation S-T [17 CFR 232.303] (specific requirements for electronically filed documents); and rule 0-4 [17 CFR 270.0-4] (additional rules on incorporation by reference for investment companies).

\* \* \* \* \*

**Item 25. Financial Statements and Exhibits**

\* \* \* \* \*

**2. Exhibits:**

\* \* \* \* \*

**Instructions**

\* \* \* \* \*

4. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

5. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

6. The registrant may redact provisions or terms of exhibits required to be filed by paragraph k. of this Item if those provisions or terms are both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is

both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

7. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 71. Amend Form N-3 (referenced in §§ 239.17a and 274.11b of this chapter) by revising General Instruction G and the Instructions to Item 29(b) to add Instructions 3, 4, 5, and 6 to read as follows:

**Note:** The text of Form N-3 does not, and this amendment will not, appear in the Code of Federal Regulations.

**FORM N-3**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

*G. Incorporation by Reference*

A Registrant may, at its discretion, incorporate all or part of the Statement of Additional Information into the prospectus, without physically delivering the Statement of Additional

Information to investors with the prospectus. But the Statement of Additional Information must be available to the investor upon request at no charge and any information or documents incorporated by reference into the Statement of Additional Information must be provided along with the Statement of Additional Information.

In general, a Registrant may incorporate by reference, in the answer to any item of Form N-3 not required to be in the prospectus, any information elsewhere in the registration statement or in other statements, applications, or reports filed with the Commission.

Subject to these rules, a Registrant may incorporate by reference into the prospectus or the Statement of Additional Information in response to Items 4(a) or 28 of Form N-3 the information in Form N-CSR [17 CFR 249.331 and 274.128] or any report to contract owners meeting the requirements of Section 30(e) of the 1940 Act [15 U.S.C. 80a-29(e)] and Rule 30e-1 [17 CFR 270.30e-1] provided:

1. The material incorporated by reference is prepared in accordance with, and covers the periods specified by, this Form.

2. The Registrant states in the prospectus or the Statement of Additional Information, at the place where the information would normally appear, that the information is incorporated by reference from a report to security holders or a report on Form N-CSR. The Registrant may also describe, in either the prospectus, the Statement of Additional Information, or Part C of the Registration Statement (in response to Item 29(a)), any parts of the report to security holders or the report on Form N-CSR that are not incorporated by reference and are not a part of the Registration Statement.

3. The material incorporated by reference is provided with the prospectus or the Statement of Additional Information to each person to whom the prospectus or the Statement of Additional Information is given, unless the person holds securities of the Registrant and otherwise has received a copy of the material. However, Registrant must state in the prospectus or the Statement of Additional Information that it will furnish, without charge, another copy of such report on request and the name, address, and telephone number of the person to contact.

All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 411 under the Securities Act [17 CFR

230.411] (general rules on incorporation by reference in a prospectus); rule 303 of Regulation S-T [17 CFR 232.303] (specific requirements for electronically filed documents); and rule 0-4 [17 CFR 270.0-4] (additional rules on incorporation by reference for investment companies).

\* \* \* \* \*

**Item 29. Financial Statements and Exhibits**

\* \* \* \* \*

(b) Exhibits:

\* \* \* \* \*

**Instructions**

\* \* \* \* \*

3. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

4. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

5. The registrant may redact provisions or terms of exhibits required to be filed by paragraphs (9) and (11) of this Item if those provisions or terms are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly

provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

6. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 72. Amend Form N-4 (referenced in §§ 239.17b and 274.11c of this chapter) by revising General Instruction G and the Instructions to Item 24(b) to add Instructions 3, 4, 5, and 6 to read as follows:

**Note:** The text of Form N-4 does not, and this amendment will not, appear in the Code of Federal Regulations.

**FORM N-4**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

*G. Incorporation by Reference*

A Registrant may, at its discretion, incorporate all or part of the Statement of Additional Information into the prospectus, without physically delivering the Statement of Additional Information to investors with the prospectus. But the Statement of Additional Information must be available to the investor upon request at no charge and any information or documents incorporated by reference into the Statement of Additional Information must be provided along

with the Statement of Additional Information.

All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 411 under the Securities Act [17 CFR 230.411] (general rules on incorporation by reference in a prospectus); rule 303 of Regulation S-T [17 CFR 232.303] (specific requirements for electronically filed documents); and rule 0-4 [17 CFR 270.0-4] (additional rules on incorporation by reference for investment companies).

In general, a Registrant may incorporate by reference, in the answer to any item of Form N-4 not required to be in the prospectus, any information elsewhere in the registration statement or in other statements, applications, or reports filed with the Commission.

\* \* \* \* \*

**Item 24. Financial Statements and Exhibits**

\* \* \* \* \*

(b) Exhibits:

\* \* \* \* \*

**Instructions**

\* \* \* \* \*

3. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

4. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

5. The registrant may redact provisions or terms of exhibits required to be filed by paragraphs (7) and (8) of this Item if those provisions or terms are both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of

the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

6. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 73. Amend Form N-6 (referenced in §§ 239.17c and 274.11d of this chapter) by revising General Instruction D.2 and in Item 26 by adding Instructions 1 through 4 to read as follows:

**Note:** The text of Form N-6 does not, and this amendment will not, appear in the Code of Federal Regulations.

**FORM N-6**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

*B. Filing and Use of Form N-6*

\* \* \* \* \*

4. What rules apply to the filing of a registration statement on Form N-6?

\* \* \* \* \*

*D. Incorporation by Reference*

\* \* \* \* \*

2. General Requirements

All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: rule 411 under the Securities Act [17 CFR 230.411] (general rules on incorporation by reference in a prospectus); rule 303 of Regulation S-T [17 CFR 232.303] (specific requirements for electronically filed documents); and rule 0-4, [17 CFR 270.0-4] (additional rules on incorporation by reference for investment companies).

\* \* \* \* \*

**Item 26. Exhibits**

\* \* \* \* \*

**Instructions**

1. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

2. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

3. The registrant may redact provisions or terms of exhibits required to be filed by paragraphs (g) and (j) of this Item if those provisions or terms are both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the

redacted exhibit that certain identified information has been excluded from the exhibit because it is both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit.

If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the procedures outlined in Rules 418 (§ 230.418 of this chapter).

4. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 74. Amend Form N-8B-2 (referenced in § 274.12 of this chapter) in "IX Exhibits" by adding Instructions 1 through 4 to read as follows:

**Note:** The text of Form N-8B-2 does not, and this amendment will not, appear in the Code of Federal Regulations.

**Form N-8B-2**

\* \* \* \* \*

IX

EXHIBITS

\* \* \* \* \*

**Instructions**

1. Schedules (or similar attachments) to the exhibits are not required to be filed provided that they do not contain

information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

2. The registrant may redact information from exhibits required to be filed if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

3. The registrant may redact provisions or terms of exhibits required to be filed by A(9) if those provisions or terms are both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. If it does so, the registrant should mark the exhibit index to indicate that portions of the exhibit or exhibits have been omitted and include a prominent statement on the first page of the redacted exhibit that certain identified information has been excluded from the exhibit because it is both (1) not material and (2) would likely cause competitive harm to the registrant if publicly disclosed. The registrant also must indicate by brackets where the information is omitted from the filed version of the exhibit. If requested by the Commission or its staff, the registrant must promptly provide an unredacted copy of the exhibit on a supplemental basis. The Commission staff also may request the registrant to provide its materiality and competitive harm analyses on a supplemental basis. Upon evaluation of the registrant's supplemental materials, the Commission or its staff may request the registrant to amend its filing to include in the exhibit any previously redacted information that is not adequately supported by the registrant's materiality and competitive harm analyses. The registrant may request confidential treatment of the supplemental material pursuant to Rule 83 (§ 200.83 of this chapter) while it is in the possession of the Commission or its staff. After completing its review of the supplemental information, the Commission or its staff will return or destroy it at the request of the registrant, if the registrant complies with the

procedures outlined in Rules 418 (§ 230.418 of this chapter).

4. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

\* \* \* \* \*

■ 75. Amend Form N-CSR (referenced in §§ 249.331 and 274.128 of this chapter) by:

- a. Revising General Instruction D;
- b. Removing "Instruction to Item 11" following paragraph (b) of Item 13 and replacing it with "Instructions to Item 13"; and
- c. Revising the text following the "Instructions to Item 13".

The revisions read as follows:

**Note:** The text of Form N-CSR does not, and this amendment will not, appear in the Code of Federal Regulations.

**Form N-CSR**

\* \* \* \* \*

**GENERAL INSTRUCTIONS**

\* \* \* \* \*

*D. Incorporation by Reference*

A registrant may incorporate by reference information required by Items 4, 5, and 12(a)(1). No other Items of the Form shall be answered by incorporating any information by reference. The information required by Items 4 and 5 may be incorporated by reference from the registrant's definitive proxy statement (filed or required to be filed pursuant to Regulation 14A (17 CFR 240.14a-1 *et seq.*)) or definitive information statement (filed or to be filed pursuant to Regulation 14C (17 CFR 240.14c-1 *et seq.*)) involving the election of directors, if such definitive proxy statement or information statement is filed with the Commission not later than 120 days after the end of the fiscal year covered by an annual report on this Form. All incorporation by reference must comply with the requirements of this Form and the following rules on incorporation by reference: Rule 303 of Regulation S-T (17 CFR 232.303) (specific requirements

for electronically filed documents); Rule 12b-23 under the Exchange Act (17 CFR 240.12b-23) (additional rules on incorporation by reference for reports filed pursuant to Sections 13 and 15(d) of the Exchange Act); and Rule 0-4 (17 CFR 270.0-4) (additional rules on incorporation by reference for investment companies).

\* \* \* \* \*

**Item 13. Exhibits**

\* \* \* \* \*

*Instructions to Item 13*

1. Letter or number the exhibits in the sequence that they appear in this item. Each exhibit identified in the exhibit index (other than an exhibit filed in eXtensible Business Reporting Language) must include an active link to an exhibit that is filed with the registration statement or, if the exhibit is incorporated by reference, an active hyperlink to the exhibit separately filed on EDGAR. If the registration statement is amended, each amendment must include active hyperlinks to the exhibits required with the amendment.

2. Schedules (or similar attachments) to the exhibits required by this Item are not required to be filed provided that they do not contain information material to an investment or voting decision and that information is not otherwise disclosed in the exhibit or the disclosure document. Each exhibit filed must contain a list briefly identifying the contents of all omitted schedules. Registrants need not prepare a separate list of omitted information if such information is already included within the exhibit in a manner that conveys the subject matter of the omitted schedules and attachments. In addition, the registrant must provide a copy of any omitted schedule to the Commission or its staff upon request.

3. The registrant may redact information from exhibits required to be filed by this Item if disclosure of such information would constitute a clearly unwarranted invasion of personal privacy (e.g., disclosure of bank account numbers, social security numbers, home addresses and similar information).

\* \* \* \* \*

**PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940**

■ 76. The authority citation for part 275 continues to read, in part, as follows:

**Authority:** 15 U.S.C. 80b-2(a)(11)(G), 80b-2(a)(11)(H), 80b-2(a)(17), 80b-3, 80b-4, 80b-4a, 80b-6(4), 80b-6a, and 80b-11, unless otherwise noted.

\* \* \* \* \*

■ 77. Revise § 275.0-6 to read as follows:

**§ 275.0-6 Incorporation by reference in applications.**

(a) *Exhibits.* Any document or part thereof, including any financial statement or part thereof, filed with the Commission pursuant to any Act administered by the Commission may be incorporated by reference as an exhibit to any application filed with the Commission by the same or any other person. If any modification has occurred in the text of any document incorporated by reference since the filing thereof, the registrant must file with the reference a statement containing the text of any such modification and the date thereof.

(b) *General.* Include an express statement clearly describing the specific location of the information you are incorporating by reference. The statement must identify the document where the information was originally filed or submitted and the location of the information within that document. The statement must be made at the particular place where the information is required, if applicable. Information must not be incorporated by reference in any case where such incorporation would render the disclosure incomplete, unclear, or confusing. For example, unless expressly permitted or required, disclosure must not be incorporated by reference from a second document if that second document incorporates information pertinent to such disclosure by reference to a third document.

(c) *Definition of Application.* For purposes of this rule, an "application" means any application for an order of the Commission under the Act other than an application for registration as an investment adviser.

By the Commission.

Dated: March 20, 2019.

**Eduardo A. Aleman,**  
*Deputy Secretary.*

[FR Doc. 2019-05695 Filed 4-1-19; 8:45 am]

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Part III

Department of Health and Human Services

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Food and Drug Administration

21 CFR Parts 16 and 1107

Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports; Proposed Rule

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 16 and 1107

[Docket No. FDA-2016-N-3818]

RIN 0910-AH89

#### Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports

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

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a proposed rule to establish requirements for the content and format of reports intended to establish the substantial equivalence of a tobacco product (SE Reports). The proposed rule would establish the information an SE Report must include so that FDA may make a substantial equivalence determination. In addition, the proposed rule would establish the general procedures FDA intends to follow when evaluating SE Reports, including procedures that would address communications with the applicant and the confidentiality of data in an SE Report. The proposed rule is intended to provide more clarity to applicants and support efficient and predictable reviews of SE Reports.

**DATES:** Submit either electronic or written comments on the proposed rule by June 17, 2019. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 2, 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 June 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://](https://www.regulations.gov)

[www.regulations.gov](https://www.regulations.gov) will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2016-N-3818 for "Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports." 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 comments on information collection issues to the Office of Management and Budget in the following ways: Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or email to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title, "Substantial Equivalence Reports for Tobacco Products."

**FOR FURTHER INFORMATION CONTACT:** Annette Marthaler or Daniel Gittleson, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

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## Executive Summary

### *Purpose of the Regulatory Action*

This proposed rule would establish requirements related to the content and format of SE Reports, including the information that SE Reports must contain. FDA is basing this proposed rule on the experience the Agency has in reviewing thousands of SE Reports since 2010. The SE Reports that FDA has seen to date range widely in the level of detail included. For example, some have very little information on the comparison of the new tobacco product with a predicate tobacco product while other SE Reports are much more detailed in describing how the new tobacco product compares to the identified predicate tobacco product and provide supporting information. This wide variation in the depth of content may be due, at least in part, to confusion about what information FDA needs from applicants to make a substantial equivalence finding. FDA's experience reviewing this wide range of SE Reports has been helpful in developing this proposed rule, which describes in detail the information that an applicant would be required to include in an SE Report.

The proposed rule also addresses issues such as communications with the applicant, the retention of records that support the SE Report, confidentiality of SE Report information, and electronic submission of the SE Report and amendments. The proposed rule is intended to provide both applicants and FDA with more certainty about the content and format of SE Reports and FDA's review of the SE Reports. The proposed rule is also intended to provide more clarity to applicants and help ensure that the SE pathway for premarket review of a new tobacco product is used when appropriate, *e.g.*, when there is a valid predicate tobacco product to which the new product can be scientifically compared and support efficient and predictable reviews.

### *Legal Authority*

This proposed rule is being issued based upon FDA's authority to require premarket review of new tobacco products under sections 905(j) and 910(a) of the Federal Food, Drug, and

Cosmetic Act (FD&C Act) (21 U.S.C. 387e(j) and 387j(a)), FDA's authority to require reports under section 909(a) of the FD&C Act (21 U.S.C. 387i(a)), FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c), as well as FDA's rulemaking and inspection authorities under sections 701(a) and 704 of the FD&C Act (21 U.S.C. 371(a) and 374).

### *Summary of the Major Provisions*

This proposed rule would establish content and format requirements for SE Reports. Under the proposed rule, an SE Report must provide information comparing the new tobacco product to a predicate tobacco product, including information that would enable FDA to uniquely identify the new tobacco product and the predicate tobacco product. The proposed requirements would help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (as required by section 910(a)(2)(A) of the FD&C Act).

In addition, the proposed rule would explain how an applicant can amend or withdraw an SE Report, and explain how an applicant may transfer ownership of an SE Report to a new applicant. The proposed rule also would address FDA communications with applicants on SE Reports, including when FDA would issue deficiency notifications; explain FDA review cycles; and identify actions that FDA may take on SE Reports. The proposed rule would address when FDA may rescind an SE order and explain how long an applicant must maintain records related to the SE Report. The proposed rule also would explain FDA's disclosure provisions and provide for electronic submission of SE Reports, unless the applicant requests a waiver. FDA is basing the proposed rule on our experience reviewing SE Reports, and the proposed rule is intended to provide both applicants and FDA with more certainty related to the information needed to demonstrate substantial equivalence and FDA's review processes with the goal of an efficient and predictable review process for SE Reports.

### *Costs and Benefits*

This proposed rule would impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from \$0.60 million to \$2.64 million, with a primary estimate of \$1.61 million at a 3 percent discount rate, and from \$0.56 million to \$2.32 million, with a primary estimate of \$1.43 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from \$0.07 million to \$0.31 million, with a primary estimate of \$0.19 million at a 3 percent discount rate and from \$0.08 million to \$0.33 million, with a primary estimate of \$0.20 at a 7 percent discount rate.

The benefits of this proposed rule are potential time-savings to industry and cost-savings to government. This proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. In this proposed rule, we intend to shorten review times for SE Reports. In addition, based on our experience with prior SE Reports, we believe this proposed rule would lead to better SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which would result in cost-savings. We estimate that the present value of government cost-savings ranges from \$15 million to \$198 million, with a primary estimate of \$62 million at a 3 percent discount rate, and from \$12 million to \$163 million, with a primary estimate of \$51 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from \$1.7 million to \$23.2 million, with a primary estimate of \$7.2 million at both 3 and 7 percent discount rates.

The qualitative benefits of this proposed rule include additional clarity to industry about the requirements for the content and format of SE Reports. The proposed rule would also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this proposed rule would make the SE pathway more predictable.

TABLE 1—SUMMARY OF ANNUALIZED COSTS AND BENEFITS OF THE PROPOSED RULE  
[\$2016 over 10 years]

	Low (3%)	Medium (3%)	High (3%)	Low (7%)	Medium (7%)	High (7%)
Costs .....	\$0.07	\$0.19	\$0.31	\$0.08	\$0.20	\$0.33
Benefits .....	1.7	7.2	23.2	1.7	7.2	23.2
Net Benefits (rounded) .....	1.7	7.1	22.9	1.7	7.0	22.9

## I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted June 22, 2009, and provided FDA the authority to regulate tobacco products under the FD&C Act. The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced into interstate commerce for commercial distribution in the United States, the new tobacco product must undergo premarket review by FDA. Section 910(a)(1) of the FD&C Act defines a “new tobacco product” as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

The FD&C Act establishes three premarket review pathways for a new tobacco product:

- Submission of a premarket tobacco application under section 910(b);
- Submission of a report intended to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product under section 905(j)(1)(A) (“SE Report”); and
- Submission of a request for an exemption under section 905(j)(3) (implemented at § 1107.1 (21 CFR 1107.1)).

Under section 910(a)(2)(B) of the FD&C Act, a manufacturer of a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, that submitted an SE Report<sup>1</sup> prior to March 23, 2011, may continue to market the tobacco product unless FDA issues an order that the

tobacco product is not substantially equivalent. For any new tobacco product introduced into commercial distribution on or after March 22, 2011, or for which a substantial equivalence report was not submitted by March 23, 2011, a manufacturer must first submit a premarket application under section 910 for the new tobacco product to FDA, and FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution. If a new tobacco product is marketed without an order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

Since 2010, FDA has received more than 5,000 premarket applications. Almost all of the premarket applications have been SE Reports. To assist manufacturers in preparing SE Reports, FDA has issued guidance documents;<sup>2</sup> conducted Webinars; met with manufacturers; posted technical project lead reviews (which describe the administrative, compliance, and substantive scientific reviews completed on a specific SE Report), general information about not substantially equivalent (NSE) determinations, and orders (FDA posts the NSE orders for provisional tobacco products,<sup>3</sup> and SE

<sup>2</sup> The guidance documents include: “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” (January 2011); “Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007” (September 2014); “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions” (December 2016); and “Meetings with Industry and Investigators on the Research and Development of Tobacco Products” (July 2016). These guidance documents may be accessed at <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

<sup>3</sup> “Provisional” tobacco products refer to those tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011, and for which a 905(j) (Substantial

orders for all tobacco products); and issued letters outlining deficiencies in individual tobacco product SE Reports. Manufacturers are now more informed about what an SE Report should contain, and FDA is more informed about the range of tobacco products and changes made to these products and the data needed to demonstrate substantial equivalence. The proposed rule is based on this experience and would establish requirements related to the substantial equivalence premarket pathway and provide both manufacturers and FDA with more certainty related to the information needed to demonstrate substantial equivalence and FDA’s review processes.

## II. Legal Authority

As described in the following paragraphs, FDA is proposing this rule to prescribe the content, form, and manner of reports intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product, as well as to establish other requirements related to SE Reports including requirements for keeping records, making reports, and providing information essential to FDA’s implementation of the FD&C Act. In accordance with section 5 of the Tobacco Control Act, FDA intends that the requirements that would be established by this proposed rule be severable and that the invalidation of any provision of this proposed rule would not affect the validity of any other part of this rule.

Section 910(a)(2) of the FD&C Act requires a new tobacco product to be the subject of a premarket tobacco application (PMTA) order unless FDA has issued an SE order authorizing its commercial distribution or the tobacco product is exempt from substantial equivalence. To satisfy the requirement of premarket review, a manufacturer may submit a report intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product under section 905(j) of the FD&C Act. Section 905(j) provides that FDA may prescribe the form and

Equivalence) Report was submitted no later than March 22, 2011.

<sup>1</sup> In this proposed rule, FDA refers to “SE applications” as “SE Reports,” but the terms both refer to a premarket submission under section 905(j)(1)(A) of the FD&C Act.

manner of the substantial equivalence report, and section 910(a)(4) requires that as part of the 905(j) report, the manufacturer provide an adequate summary of any health information related to the new tobacco product or state that such information will be made available upon request.

Based on the information provided by the applicant, section 910(a)(3)(A) of the FD&C Act authorizes FDA to issue an order finding substantial equivalence when FDA finds that the new tobacco product is in compliance with the requirements of the FD&C Act and either: (1) Has the same characteristics as the predicate tobacco product or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to regulate the product under (the premarket tobacco application or "PMTA" provisions) because the product does not raise different questions of public health.

Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to maintain such records, make such reports, and provide such information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health.

Under section 902(6)(A) of the FD&C Act, a tobacco product is adulterated if it is required to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act. Under section 903(a)(6) of the FD&C Act, a tobacco product is misbranded if a notice or other information respecting it was not provided as required by section 905(j) of the FD&C Act. In addition, a tobacco product is misbranded if there is a failure or refusal to furnish any material or information required under section 909 (section 903(a)(10)(B) of the FD&C Act).

Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act, and section 704 of the FD&C Act provides FDA with general inspection authority.

### III. Description of Proposed Regulations

The proposed rule would add subparts B through E to current part 1107 of Title 21. The requirements set out in this proposed rule would not apply to provisional SE Reports or to any SE Report submitted before the effective date of any final rule associated with this proposed

rulemaking. FDA has published a final rule extending the Agency's "tobacco product" authorities in the FD&C Act to all categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products ("Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (81 FR 28974, May 10, 2016) (the Deeming final rule)). This proposed rule would apply to SE Reports for all tobacco products submitted after the final rule is effective, including the newly deemed tobacco products, that FDA regulates under Chapter IX of the FD&C Act. Proposed subparts D and E set out FDA's review processes and would be applicable to FDA's review of SE Reports after the effective date of any final rule. The proposed rule also would amend § 16.1 (21 CFR 16.1) to add a reference to proposed § 1107.50 (this proposed section would address rescission of an SE order).

#### A. General (Proposed Subpart B)

##### 1. Scope (Proposed § 1107.10)

According to proposed § 1107.10, subparts B through E would establish the procedures and requirements for the submission of an SE Report under sections 905 and 910 of the FD&C Act, the basic criteria for establishing substantial equivalence, and the general procedures FDA intends to follow when evaluating SE Reports.

##### 2. Definitions (Proposed § 1107.12)

Proposed § 1107.12 sets forth the meaning of terms as they apply to proposed subparts B through E of part 1107. Proposed § 1107.12 includes the following definitions from the FD&C Act:

- *Additive*. As defined in section 900(1) of the FD&C Act (21 U.S.C. 387), "additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

An additive can be a type of ingredient in a tobacco product; an example is methyl salicylate in smokeless tobacco, which can serve as an absorption enhancer and affect the characteristics of the tobacco product by changing the rate of absorption into the body. Tobacco is not an additive.

- *Brand*. As defined in section 900(2) of the FD&C Act, "brand" means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

- *Characteristic*. As defined in section 910(a)(3)(B) of the FD&C Act, "characteristic" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product. All of the terms used in the definition of characteristic (materials, ingredients, design, etc.) are defined in proposed § 1107.12.

- *Distributor*. As defined in section 900(7) of the FD&C Act, "distributor" means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

- *New tobacco product*. As defined in section 910(a)(1) of the FD&C Act, "new tobacco product" means: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Under the FD&C Act, and as reflected in the proposed definition, new tobacco products include those that are new because they have been rendered new through any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (21 U.S.C. 387j(a)(1)(B)). For example, modifications to cigarette paper, container closure systems (*e.g.*,

change from glass to plastic e-liquid vials or from plastic to tin container closures), product quantity, specifications that change characteristics (e.g., a modification to a different tobacco cut size) would render a tobacco product new.

Manufacturers sometimes co-package tobacco products. Co-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product. Examples include a carton of cigarette packs and a variety pack of three smokeless tins shrink-wrapped together where the cigarette packs and smokeless tins, respectively, could be legally marketed separately. However, if a manufacturer wishes to co-package two or more tobacco products (including their respective container closure systems), premarket review is required for any new tobacco product that the manufacturer intends to include in the co-package. An example includes shrink-wrapping grandfathered tobacco filler (in its unmodified container closure system) with new rolling papers; here premarket authorization would be required for the rolling papers. In addition, co-packaging two or more tobacco products within the same container closure system results in a new tobacco product, unless such co-packaged product is grandfathered. Examples include an RYO kit where rolling papers are placed inside the tin of tobacco filler and shrink-wrapping together two soft-packs of cigarettes, neither of which had been individually shrink-wrapped prior to being co-packaged. FDA invites comment on approaches to its review of these types of SE Reports, including, where relevant, how co-packaging products impacts consumer use and behavior.

In addition, for purposes of determining whether a tobacco product is new under section 910 of the FD&C Act, and therefore requires premarket authorization prior to marketing, a “tobacco product” can be considered to encompass the whole product (e.g., a pack of cigarettes or a tin of loose tobacco), and is not limited to a single unit or portion of the whole product (e.g., a single cigarette or a single snus pouch). See *Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, 202 F. Supp. 3d 31, 55–57 (D.D.C. 2016). Consequently, a change in product quantity (e.g., decreasing the weight of a smokeless package from 24 grams to 15 grams) results in a new tobacco product subject to premarket review since such a modification “necessarily entails a change in the amount of the

constituent ingredients and additives within the tobacco product, including nicotine” (id. at 56).

FDA also considers a tobacco product marketed exclusively in test markets on February 15, 2007, to be a new tobacco product that is subject to premarket review by FDA. In addition, such test marketed products cannot serve as valid predicate products in an SE Report. A tobacco product that the applicant intends to test market after February 15, 2007, is also a new tobacco product subject to premarket review under section 910(a) of the FD&C Act because it was not commercially marketed in the United States as of February 15, 2007.

Because the terms “test marketing” and “commercially marketed” are not interchangeable, FDA is considering whether it would be useful to applicants for the rule to further expand on or define the terms “test marketing” and “commercially marketed.” Specifically, FDA is considering whether to add the following definition of test marketing: “test marketing” means distributing or offering for sale (which may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply:

- Offered in a limited number of regions;
- Offered for a limited time; or
- Offered to a chosen set of the population or specific demographic group.

FDA is considering whether to define “commercially marketed” as offering a tobacco product for sale to consumers in all or in parts of the United States. Factors FDA may consider include advertising or other means used to communicate that the tobacco product was available for purchase, including dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated manufacturing documents, inventory lists, or any other document that demonstrates that the product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007. FDA invites comment on what evidence would be sufficient to demonstrate that a product was commercially marketed (other than in test markets) as of February 15, 2007.

FDA is inviting comments on: (1) Whether the rule should further expand on the interpretation or include

definitions of these terms, (2) the substance of the definitions, if included, and (3) whether or not the approach described is adequate to protect the public health.

- *Package or packaging.* As defined in section 900(13) of the FD&C Act, “package” or “packaging” means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers. A subset of package is the container closure system (also defined in this proposed rule). For example, the carton holding multiple soft packs of cigarettes is considered the package, and each soft pack with surrounding cellophane is considered the container closure system. Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (e.g., leaching substances that are then incorporated into a tobacco product), but packaging that is not the container closure system is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product.

- *Substantial equivalence or substantially equivalent.* As defined in section 910(a)(3)(A) of the FD&C Act, the term “substantial equivalence” or “substantially equivalent” means, with respect to the tobacco product being compared to the predicate tobacco product, that FDA, by order, has found that the tobacco product:

- Has the same characteristics as the predicate tobacco product or
- Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA that demonstrates that it is not appropriate to require premarket review under section 910(a), (b) and (c) of the FD&C Act because the product does not raise different questions of public health.

FDA notes that this proposed rule does not include a proposed interpretation of “same characteristics” and “different characteristics” under section 910(a)(3)(A) of the FD&C Act.<sup>4</sup> However, FDA recognizes that stakeholders have requested additional clarity on these terms. FDA continues to consider the appropriate implementation of these terms, as well as public feedback the Agency has received on the terms during workshops

<sup>4</sup> FDA notes that products with identical characteristics are not new products, and thus are not required to undergo premarket review.

and in response to other **Federal Register** notices (e.g., most recently, in response to a notice related to the Paperwork Reduction Act, 83 FR 45251, September 6, 2018). For example, FDA is considering whether the “same characteristics” prong might be appropriate for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health. Examples of changes between the new and predicate products that might be appropriate to proceed through “same characteristics,” either individually or in combination, include, non-exhaustively: (1) A change in product quantity between the new and predicate tobacco products; (2) a change in container closure system for non-moist tobacco products; (3) decreases in the total amount of tobacco in the new tobacco product without any corresponding changes in other ingredients or characteristics of the new tobacco product; and (4) changes in the non-combusted portion of a cigarette, for example, a change in tipping paper color from plain to cork, or a change in adhesive, or the removal of a dye or ink.

Under this approach, a new product would have “different characteristics” if a product were dissimilar enough from the predicate product that FDA could not determine without scientific information whether the new product raised different questions of public health. Examples of changes between the new and predicate products that might be appropriate to proceed through “different characteristics,” either individually or in the aggregate, include, non-exhaustively:

- A change in filter or ventilation of a combusted tobacco product, because such a change has the potential to affect the public health analysis required to assess substantial equivalence, such that FDA would need scientific information to determine whether the new product raises different questions of public health. For example, in some circumstances, a change in filter could result in an increase in ventilation and a change in harmful or potentially harmful constituent (HPHC) exposure levels to the user, with effects on the public health impact of the product. It is possible that in some other circumstances, a change in filter would not have results that would affect the public health impact of the product.

- A change in container closure system for a moist smokeless tobacco product, because FDA would need scientific information to determine, for example, whether or not such

differences could result in a change in tobacco product stability that would increase HPHC levels and exposures to the user.

- A change in characterizing flavor in the new product because FDA would need scientific information to determine, for example, whether or not such differences could affect use behaviors.

FDA notes that these examples are illustrative only and are not intended to convey that any differences specific to an individual case would or would not be appropriate to proceed through the “different characteristics” approach or result in a determination of SE.

When a new product has different characteristics, FDA would evaluate whether the difference(s) in characteristics, individually and in the aggregate, do not cause the new product to raise different questions of public health. In determining if a new product raises different questions of public health, FDA may consider, among other things, whether one or more of the following is the case, as compared to the predicate product, (1) the new product has the potential to increase HPHC yields, and, if so, the degree of such an increase; (2) the new product has the potential to increase toxicity; (3) the new product has the potential to increase initiation; (4) the new product has the potential to increase abuse liability; (5) the new product has the potential to increase dependence; or (6) the new product has the potential to decrease cessation. Based on this analysis, FDA will determine whether the applicant has demonstrated that any differences do not cause the new product to raise different questions of public health.

Please note that FDA is including these examples based on the Agency’s experience to date in reviewing SE reports, and for purposes of soliciting comments on this approach, and FDA will continue to review each SE Report and make an SE determination on the basis of the information included in that SE Report. FDA invites comment on the terms “same characteristics” and “different characteristics,” the potential approach discussed above, and any alternative approaches to interpretation of these terms, including examples of new tobacco products that would have the “same characteristics” as the predicate, as well as new tobacco products that would have “different characteristics” from the predicate. While the rule proposes that certain information would be required for reports submitted under either the same characteristics or different characteristics prong, we welcome

comments on what information would need to be included under either or both prongs if the approach described above, or an alternative approach, is implemented. FDA also invites comment on how we might evaluate different questions of public health. In your comment, please include your reasoning for how you would distinguish the scope of the same characteristics prong from the different characteristics prong, *i.e.*, when an applicant might claim that a proposed new tobacco product is substantially equivalent to a predicate tobacco product because it has the “same” characteristics. FDA will consider all comments and will seek to provide additional clarity in the final rule, if possible.

- **Tobacco product.** As defined in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), the term “tobacco product” means any product that is made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term “tobacco product” does not mean an article that is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). As explained in the definition of “new tobacco product,” FDA’s interpretation is that the tobacco product encompasses the whole product and is not limited to a single unit or portion of the whole product.

- **Tobacco product manufacturer.** As defined in section 900(20) of the FD&C Act, the term “tobacco product manufacturer” means any person, including a repacker or relabeler, who: (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product or (2) imports a finished tobacco product for sale or distribution in the United States. FDA interprets “manufactures, fabricates, assembles, processes, or labels” as including, but not being limited to: (a) Repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package; (b) reconstituting tobacco leaves; or (c) applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. Manufacturing activities typically do not include the activities of destemming, drying, or packaging tobacco leaves; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaves with nothing other than potable water in the

form of steam or mist. A proposed definition for the term “finished tobacco product” is also included in the proposed rule.

In addition, FDA proposes the following definitions:

- *Accessory.* FDA proposes to define “accessory” as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

- Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or
- Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but solely controls moisture and/or temperature of a stored product; or solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Examples of accessories are ashtrays and spittoons because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. This proposed definition is also in accord with the definition included in the Deeming final rule.

- *Applicant.* FDA proposes to define “applicant” as any manufacturer of tobacco products who is subject to chapter IX of the FD&C Act that submits a premarket application to receive marketing authorization for a new tobacco product. For the purposes of part 1107, a premarket application refers to an SE Report or an exemption request.

- *Commercial distribution.* FDA proposes to define “commercial distribution” as any distribution of a tobacco product to consumers or to another person through sale or otherwise. This term does not include transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such products are not made available for consumption or resale. This term would exclude the handing or transfer of a tobacco product from one

consumer to another for personal consumption. For foreign establishments, the term “commercial distribution” has the same meaning except the term does not include distribution of any tobacco products that are neither imported nor offered for import into the United States. This term is intended to include a tobacco product that is test marketed after February 15, 2007, and this term would encompass distribution of free samples (*e.g.*, smokeless products). FDA intends to limit our enforcement of the requirements of section 910 and 905(j) to finished tobacco products (see the Guidance for Industry and FDA Staff entitled “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” (76 FR 789, January 6, 2011); see also Deeming final rule, 81 FR at 29019).

- *Component or part.* FDA proposes to define “component or part” as any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product’s performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product. A container closure system (which would also be defined in this proposed section) is considered a component or part. With respect to these definitions, FDA notes that “component” and “part” are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this proposed rule, FDA is using the terms “component” and “part” interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between “component” and “part” in the future. This proposed definition and approach are in accord with the Deeming final rule. FDA invites comments on this approach.

- *Composition.* FDA proposes to define “composition” as all of the materials in a tobacco product, including ingredients, additives, and biological organisms. The term also includes the manner in which these ingredients, additives, biological organisms, etc., are arranged and integrated to produce a tobacco product. Composition refers primarily to the chemical and biological properties of a tobacco product, whereas design refers to the physical properties of a tobacco product. A biological organism refers to any living biological entity, such as an animal, plant, fungus, or bacterium.

- *Constituent.* FDA proposes to define “constituent” as any chemical or chemical compound in a tobacco

product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission from a tobacco product, or any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the tobacco product to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product. Examples of constituents include harmful or potentially harmful constituents, total particulate matter, nicotine-free dry particulate matter, and water. A constituent also could include any other chemical or chemical compound contained in or produced by a tobacco product under conditions of use.

- *Container closure system.* FDA proposes to define “container closure system” as any packaging materials that are a component or part of a tobacco product.

Examples of a container closure system include the blister pack around a dissolvable tablet (in this example, if there is a box around a blister pack, the box is not considered a container closure system if it is not intended or reasonably expected to alter or affect the dissolvable tablet), the can that contains and protects a moist snuff product, and the plastic-wrapped hard pack or soft pack used to contain and protect cigarettes. In the context of determining whether a product is substantially equivalent as defined in section 910(a)(3)(A) of the FD&C Act, a container closure system is a component or part of a tobacco product because of its potential to alter or affect the performance, composition, constituents, or other physical characteristics of the product. For example, if a change in the container closure system could affect the chemistry of the product, FDA could require the applicant to demonstrate that the change in the container closure system does not cause the new tobacco product to raise different questions of public health. Although the FD&C Act does not itself define “component” or “part,” FDA recently promulgated definitions for these terms in the Deeming final rule. According to 21 CFR 1100.3, “component or part” means any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product’s performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory

of a tobacco product.<sup>5</sup> The same definitions are also reflected in this rule's proposed § 1107.12.

In addition, considering a distinct subset of packaging (*i.e.*, container closure system) to be a component or part is consistent with the FD&C Act. For example, section 900(1) of the FD&C Act defines an "additive" as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substance intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. This definition further evinces Congress's understanding that packaging is not entirely separable from the tobacco product. Finally, the definition of "package" in section 900(13) of the FD&C Act does not dictate a contrary result, and can be reasonably interpreted to mean that a distinct subset of packaging is also a component or part of a tobacco product.

According to the proposed definition above, packaging constitutes a container closure system if it is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product, even if it is also used to protect or contain the tobacco product. For example, packaging materials constitute a container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, *e.g.*, when the manufacturer changes the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and TSNA formation during storage. Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 1). Packaging materials may also be intended or reasonably expected to

affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in packaging materials may also diffuse into snuff and affect its characteristics (Ref. 2). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.*, a plastic versus a metal container of smokeless tobacco). A difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine and the carcinogens N-nitrosornicotine (NNN) or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (Ref. 26).

Treating a distinct subset of packaging as a component or part thus furthers the fundamental purpose of the Tobacco Control Act to protect the public health. This interpretation is also consistent with the broad definition of "tobacco product," as well the definition of "additive," which includes any substance that may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any tobacco product—and not just substances that do *in fact* have such effects. This shows that Congress did not intend for FDA to be required to show that a container closure system did in fact alter or affect the tobacco product's performance, composition, constituents, or other characteristics. Indeed, if FDA were to adopt a narrow construction of "tobacco product" to exclude these materials, the Agency's ability to evaluate whether the differences between the new and predicate tobacco product cause the new tobacco product to raise different questions of public health would be impeded, thereby leaving the Agency unable to fully execute its mission to protect the public health.

- *Design.* FDA proposes to define "design" to mean the form and structure concerning, and the manner in which, components or parts, ingredients, software, and materials are integrated to produce a tobacco product. This term refers to the physical properties of a tobacco product. Examples of design features include tip ventilation, paper porosity, tobacco cut width, and filter efficiency.

- *Finished tobacco product.* FDA proposes to define "finished tobacco product" to mean a tobacco product, including all components and parts, sealed in final packaging (*e.g.*, filters or

filter tubes sold separately to consumers or as part of kits).

- *Grandfathered tobacco product.* FDA proposes to define a "grandfathered tobacco product" to mean a tobacco product that was commercially marketed in the United States on February 15, 2007. This term does not include tobacco products exclusively marketed in a test market as of that date. FDA interprets the phrase "as of February 15, 2007," as meaning that the tobacco product was commercially marketed in the United States "on February 15, 2007," and the proposed definition reflects this interpretation (see the final guidance entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (79 FR 58358, September 29, 2014)). A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the FD&C Act.

- *Harmful or potentially harmful constituent (HPHC).* FDA proposes to define "harmful or potentially harmful constituent" as any chemical or chemical compound in a tobacco product or tobacco smoke or emission that: (1) Is or that potentially could be inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission and (2) causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

FDA has previously discussed HPHCs in FDA guidance documents (see the final guidance entitled "Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act" (76 FR 5387, January 31, 2011; revised guidance issued August 2016)). The current established list of HPHCs can be found on FDA's website at <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297786.htm> (77 FR 20034, April 3, 2012). In addition, since the inception of the SE program for tobacco products, HPHCs have been considered "other features," and the proposed definition of "other features" in this rule would include HPHCs (see the final guidance entitled "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products," (January 5, 2011)).

- *Health information summary.* FDA proposes to define "health information summary" to mean a summary, submitted by the applicant under section 910(a)(4) of the FD&C Act, of any health information related to the new tobacco product. This would

<sup>5</sup> "Accessory" is defined as any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but solely controls moisture and/or temperature of a stored tobacco product or solely provides an external heat source to initiate but not maintain combustion of a tobacco product (§ 1100.3).

include detailed information concerning adverse health effects of the new tobacco product. For example, information concerning adverse health effects includes specific adverse events that have been reported to the applicant and also includes any research or data concerning adverse health effects of which the applicant is aware.

- *Health information statement.* FDA proposes to define “health information statement” to mean a statement, made under section 910(a)(4) of the FD&C Act that health information related to the new tobacco product would be made available upon request by any person. Like the health information summary, the health information provided to a person requesting it would be required to include any health information related to the new tobacco product, including detailed information regarding data concerning adverse health effects of the new tobacco product.

- *Heating source.* FDA proposes to define “heating source” as the source of energy that is used to burn or heat a tobacco product. An example of a heating source is a flame.

- *Ingredient.* FDA proposes to define “ingredient” as tobacco, substances, compounds, or additives added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing. For example, an ingredient may be a single chemical substance, leaf tobacco, or the product of a reaction, such as a chemical reaction, in manufacturing. Examples of substances and compounds (ingredients) reasonably expected to be formed through a chemical reaction during tobacco product manufacturing include the following:

- The reaction of sugars with amines to form families of compounds with new carbon-nitrogen bonds, including Maillard reaction products and Amadori compounds.

- The reaction of sodium hydroxide with citric acid to form sodium citrate.

- The production of ethyl alcohol, a residual solvent, from ethyl acetate during production of tipping paper adhesive.

- Products of thermolytic reactions, such as the production of carboxylic acids from sugar esters.

- Products of enzymatically or nonenzymatically catalyzed reactions, such as the hydrolytic production of flavor or aroma precursors from nonvolatile glucosides.

- Products of acid-base reactions, such as removal of a proton from

protonated nicotine to generate the basic form of nicotine (“free” nicotine).

- *Material.* FDA proposes to define “material” to mean an assembly of ingredients. Materials are assembled to form the tobacco product or components or parts of tobacco products. For example, material would include the glue or paper pulp for a cigarette where the paper pulp includes multiple ingredients (e.g., multiple types of tobacco, water, and flavors) assembled into the paper (or pulp depending on the water content).

- *Other features.* FDA proposes to define “other features” to mean any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the FD&C Act. The definition would include: (1) HPHCs (note that the definition of new tobacco product includes any modification to any constituents, including smoke constituents, section 910(a)(1)(B) of the FD&C Act) and (2) any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product that are necessary for SE Report review. As described in the proposed definition of HPHC, HPHC information is necessary to provide a complete comparison between the new and predicate tobacco products: HPHCs are a subset of the chemical and chemical compounds in a tobacco product or tobacco smoke or emission. As such, HPHC information for the new and predicate tobacco products is necessary for FDA to determine whether the new tobacco product raises different questions of public health. Other features also would encompass other product characteristics that relate to the chemical, biological, and physical properties that would not be addressed as a material, ingredient, design, composition, or heating source.

- *Predicate tobacco product.* FDA proposes to define “predicate tobacco product” to mean a tobacco product that is a grandfathered tobacco product or a tobacco product that FDA has previously found to be substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act. This proposed definition is also based on language in section 905(j)(1)(A)(i) of the FD&C Act.

- *Submission tracking number or STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and requests for grandfather determinations.

- *Substantial equivalence report or SE Report.* FDA proposes to define “substantial equivalence report” (also known as a 905(j) report) or SE Report to mean a submission under section

905(j)(1)(A)(i) of the FD&C Act that includes the basis for the applicant’s determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial SE Report and all subsequent amendments (e.g., amendments include information an applicant submits in response to a deficiency letter).

#### *B. Substantial Equivalence Reports (Proposed Subpart C)*

##### 1. Submission of a Substantial Equivalence Report (Proposed § 1107.16)

Proposed § 1107.16 explains the basic timeframes that would be required for submitting an SE Report to FDA before commencing commercial distribution of a new tobacco product. An applicant may submit an SE Report to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product (an applicant could also consider whether the exemption under § 1107.1 or an application under section 910(b) of the FD&C Act is a more appropriate premarket pathway for the applicant’s new tobacco product). If an applicant chooses to submit an SE Report for a new tobacco product, it must do so at least 90 calendar days before the date the applicant intends to begin commercial distribution of the product (see section 905(j)(1) of the FD&C Act). The proposed rule also provides that an applicant may not begin commercial distribution of the new tobacco product that is the subject of the SE Report until FDA has issued an order stating that the Agency has determined that the new tobacco product is substantially equivalent to a predicate tobacco product (unless the new tobacco product has received authorization to be marketed through another premarket pathway, *i.e.*, PMTA or exemption from substantial equivalence). Otherwise, the new tobacco product is both adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act) and subject to enforcement action.

##### 2. Required Content and Format of an SE Report (Proposed § 1107.18)

Since March 22, 2011 (the date that SE Reports for provisional tobacco products were required to be submitted), FDA has gained considerable experience in reviewing more than 3,000 SE Reports submitted under sections 905(j) and 910(a) of the FD&C Act. As a result, FDA has identified information essential to the review of SE Reports, which is reflected

in the content and format requirements of proposed § 1107.18.

a. *Overview.* Proposed § 1107.18(a) provides an overview of the requirements for the content and format of an SE Report. Proposed § 1107.18(a) would provide that the SE Report include information that would enable FDA to uniquely identify the new tobacco product and the predicate tobacco product and compare the new tobacco product to a predicate tobacco product. This information is necessary for FDA both in reviewing the SE Report so that we can understand the comparison and also to issue an order that appropriately identifies the tobacco product that is subject to the order. Providing sufficient information as described in proposed § 1107.18 would help enable FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (as required by section 910(a)(2)(A) of the FD&C Act).

The proposed provision would require that the SE Report contain the following elements:

- General information (described in proposed § 1107.18(c));
- Summary (described in proposed § 1107.18(d));
- New tobacco product description (described in proposed § 1107.18(e));
- Predicate tobacco product description (described in proposed § 1107.18(f)). This would include a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the STN of the SE order finding the predicate tobacco product SE, or the STN of, or specific information sufficient to support, a grandfathered determination of the predicate tobacco product. If the SE Report includes information on the grandfathered status of the predicate tobacco product (but FDA has not yet made a grandfathered determination<sup>6</sup>), FDA would make the grandfathered determination before beginning substantive scientific review of the SE Report to ensure that the predicate tobacco product is valid;
- Comparison information (described in proposed § 1107.18(g));
- Comparative testing information (described in proposed § 1107.18(h))

<sup>6</sup> FDA discusses the information the Agency will consider, along with Agency's general thinking on grandfathered determinations, in the guidance document, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (79 FR 58358, September 29, 2014).

- Statement of compliance with applicable tobacco product standards under section 907 of the FD&C Act (21 U.S.C. 387g) (described in proposed § 1107.18(i));

- Health summary or statement regarding the availability of such information as required by section 910(a)(4) of the FD&C Act (described in proposed § 1107.18(j));

- Compliance with part 25 (21 CFR part 25) (environmental impact considerations) (described in proposed § 1107.18(k)); and

- Certification statement (described in proposed § 1107.18(l)).

If the SE Report were missing any of these items, the Agency would, under proposed § 1107.44(a), refuse to accept the SE Report for review.

b. *General Format.* Proposed § 1107.18(b) provides the general requirements for the format of the SE Report and would require the applicant to submit the SE Report with the appropriate FDA form (Refs. 3 and 4). Proposed § 1107.18(b) would require the SE Report and any amendments to contain a comprehensive index and table of contents and be well organized, legible, and written in the English language. For any foreign language documents, the original foreign language document must be accompanied by the English translation and a certification by the applicant or responsible official authorized to represent the applicant that the translation into English is accurate. The comprehensive index would include the listing of files and data associated with those files (e.g., for an SE Report that is electronically submitted, the comprehensive index would include the listing of files and associated metadata).

As described in proposed § 1107.62, FDA is proposing that, for an SE Report and supporting documents to be accepted by FDA, the SE Report and documents must be submitted to FDA in an electronic format that the Agency can process, read, review, and archive, unless the Agency has previously granted a waiver from these requirements. FDA will not act on an SE Report until the Center for Tobacco Product's (CTP's) Document Control Center has received an SE Report that the Agency can process, read, review, and archive. Applicants that are unable to submit their reports in electronic format would be advised to consult proposed § 1107.62, which explains how the applicant may obtain a waiver from the electronic filing requirement. FDA intends to provide information on our website about technical specifications related to submission, including the electronic formats, which

would allow FDA to process, read, review, and archive the SE Report. Providing technical specifications information on our website enables FDA to periodically update the electronic formats that we are capable of accepting so that we can accommodate quickly evolving technology.

The requirements in proposed § 1107.18(b) and 1107.62 are intended to address some of the problems we have seen with SE Reports. For example, some SE Reports have been submitted to FDA in a proprietary format or password protected without providing FDA access or password information. Following up with an applicant to obtain access or password information takes time and contributes to delays. In addition, some electronic submissions have not been in a static format, and thus, the pages reformat, renumber, re-bullet, or re-date each time the document is accessed. Receiving SE Reports with these issues affects our ability to cross-reference, share, and efficiently evaluate information. Lastly, because FDA is required under regulations governing Federal records to maintain many files long term, and in a "sustainable" format (for more information on sustainable formats, please refer to National Archives and Record Administration Bulletin 2014-04, <https://www.archives.gov/records-mgmt/bulletins/2014/2014-04.html>), proposed § 1107.18(b) would ensure that these files can be managed, opened, and read by the Agency for the duration of the retention period.

c. *General information.* Proposed § 1107.18(c) lists the information that the SE Report would be required to include. This information includes general administrative information that must specify the type of submission (e.g., SE Report); the new tobacco product with unique identification and the predicate tobacco product with unique identification (to enable us to identify the new tobacco product as well as identify the predicate product), as well as contact information. The SE Report must include the following information using the FDA-provided forms, as appropriate:

- The date the SE Report is submitted (using the applicant-generated submittal date, i.e., the date the applicant assigns to it, which for a paper submission is the date typically located at the top of a cover letter, and for an electronic submission is the date when the document is uploaded to FDA's electronic submission system);
- Type of submission (e.g., SE Report or amendment to an SE Report);
- Previously assigned FDA STN, where applicable (e.g., in cases where

the applicant is submitting an amendment to an SE Report, the Agency has assigned a number in advance, or the applicant is referencing a previously denied SE Report);

- Any other relevant FDA STN, such as a request for a grandfathered determination, and cross-references to meetings regarding the new tobacco product (e.g., if FDA issues an order denying marketing authorization for a tobacco product and meets with the applicant about it before the applicant submits a new SE Report, the meeting should be referenced in the new SE Report);

- The name, address, and contact information for the applicant and the authorized representative or authorized U.S. agent (for a foreign applicant). FDA would require identification of an authorized representative or, for foreign applicants, authorized U.S. agent to help FDA ensure adequate notice is provided to applicants of official Agency communications. In particular, FDA may be unable to confirm that adequate notice of Agency action or correspondence concerning premarket

submissions is provided to foreign applicants as FDA cannot necessarily confirm receipt of correspondence sent internationally. Accordingly, the designation of a U.S. agent provides an official contact to the Agency who can receive the information or documentation on behalf of the applicant. Providing notice regarding that SE Report to the U.S. agent would constitute notice to the foreign applicant. FDA requires identification of a U.S. agent to assist FDA in communicating with the foreign applicant and help permit the Agency to efficiently process SE Reports and avoid delays. In many instances during the SE Report review process, FDA has reached out numerous times to a foreign applicant and has either been unable to speak with the applicant or was unable to directly communicate questions and/or concerns. This impediment has resulted in delays or terminations in the review of specific SE Reports and a slowdown of the premarket application process as a whole. A U.S. agent would act as a communications link between FDA and the applicant and would

facilitate timely correspondence between FDA and foreign applicants, including responding to questions concerning pending applications and, if needed, assisting FDA in scheduling meetings with the foreign applicants to resolve outstanding issues before agency action is taken. In addition, the authorized representative or U.S. agent would be authorized to act on behalf of the applicant for that specific SE Report.

- For both the new and predicate tobacco product, information needed to uniquely identify the products, including:
  - The manufacturer;
  - Product name, including the brand and sub brand;
  - Product category; product subcategory; and product properties, as provided in table 2. The applicant would select and provide for both the new and predicate tobacco products the appropriate category, subcategory, and product properties (if the product does not have a listed product property, e.g., ventilation or characterizing flavor, the report must state “none” for that property):

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION

Tobacco product category	Tobacco product subcategory	Product properties
Cigarettes .....	Combusted, Filtered .....	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 millimeter (mm), 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing Flavor(s) <sup>7</sup> (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Combusted, non-filtered .....	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Characterizing Flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Combusted, Other .....	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing Flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Non-Combusted (e.g., a cigarette where the tobacco is only heated not burned).	—Package type (e.g., hard pack, soft pack, clam shell).  —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing Flavor(s) (e.g., none, menthol). —Source of energy (e.g., charcoal, electrical heater). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Cigarette, Co-Package .....	—For a new co-packaged tobacco product composed of multiple cigarette tobacco products, include, as applicable, all properties for each individual tobacco product, as identified above.
Roll-Your-Own (RYO) Tobacco Products.	RYO Tobacco Filler .....	—Package type (e.g., bag, pouch).

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	Rolling Paper .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 20 g, 40 g).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., bag, box, booklet).</li> <li>—Product quantity (e.g., 50 sheets, 200 papers).</li> <li>—Length (e.g., 79 mm, 100 mm, 110 mm).</li> <li>—Width (e.g., 28 mm, 33 mm, 45 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Filtered Cigarette Tube .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity (e.g., 100 tubes, 200 tubes).</li> <li>—Length (e.g., 89 mm, 100 mm).</li> <li>—Diameter (e.g., 6 mm, 8.1 mm).</li> <li>—Ventilation (e.g., none, 10%, 25%).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Non-Filtered Cigarette Tube .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity (e.g., 100 tubes, 200 tubes).</li> <li>—Length (e.g., 89 mm, 100 mm).</li> <li>—Diameter (e.g., 6 mm, 8.1 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Filter .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity (e.g., 100 filters, 200 filters).</li> <li>—Length (e.g., 8 mm, 12 mm).</li> <li>—Diameter (e.g., 6 mm, 8.1 mm).</li> <li>—Ventilation (e.g., none, 10%, 25%).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Paper Tip .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity (e.g., 200 tips, 275 tips).</li> <li>—Length (e.g., 12 mm, 15 mm).</li> <li>—Width (e.g., 27 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	RYO Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple RYO tobacco products, include, as applicable, all properties for each individual tobacco product (e.g., RYO tobacco, rolling paper, filtered cigarette tube, non-filtered cigarette tube, filter, paper tip) as identified above.</li> </ul>
	Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
Smokeless Tobacco Products .....	Loose Moist Snuff .....	<ul style="list-style-type: none"> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> <li>—Product quantity (e.g., 20 grams (g), 2 ounces).</li> <li>—Tobacco cut size (e.g., 5 mm, 7 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Portioned Moist Snuff .....	<ul style="list-style-type: none"> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> <li>—Product quantity (e.g., 22.5 g, 20 g).</li> <li>—Portion count (e.g., 15 pouches, 20 pieces).</li> <li>—Portion mass (e.g., 1.5 g/pouch, 2 g/piece).</li> <li>—Portion length (e.g., 15 mm, 20 mm).</li> <li>—Portion width (e.g., 10 mm, 15 mm).</li> <li>—Portion thickness (e.g., 5 mm, 7 mm).</li> <li>—Tobacco cut size (e.g., 5 mm, 7 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Loose Snus .....	<ul style="list-style-type: none"> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> </ul>

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
ENDS (Electronic Nicotine Delivery System).	Portioned Snus .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 20 g, 2 ounces).</li> <li>—Tobacco cut size (e.g., 5 mm, 7 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> </ul>
	Loose Dry Snuff .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 22.5 g, 20 g).</li> <li>—Portion count (e.g., 15 pouches, 20 pieces).</li> <li>—Portion mass (e.g., 1.5 g/pouch, 2 g/piece).</li> <li>—Portion length (e.g., 15 mm, 20 mm).</li> <li>—Portion width (e.g., 10 mm, 15 mm).</li> <li>—Portion thickness (e.g., 5 mm, 7 mm).</li> <li>—Tobacco cut size (e.g., 5 mm, 7 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> </ul>
	Dissolvable .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 20 g, 2 ounces).</li> <li>—Tobacco cut size (e.g., 0.05 mm, 0.07 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> </ul>
	Loose Chewing Tobacco .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 22.5 g, 20 g).</li> <li>—Portion count (e.g., 15 sticks, 20 tablets).</li> <li>—Portion mass (e.g., 1.5 g/strip, 1.0 g/piece).</li> <li>—Portion length (e.g., 10 mm, 15 mm).</li> <li>—Portion width (e.g., 5 mm, 8 mm).</li> <li>—Portion thickness (e.g., 3 mm, 4 mm).</li> <li>—Tobacco cut size (e.g., 0.05 mm, 0.07 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., bag, pouch, wrapped).</li> </ul>
	Portioned Chewing Tobacco .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 20 g, 3 ounces).</li> <li>—Tobacco cut size (e.g., 0.05 mm, 0.07 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> </ul>
	Smokeless Co-Package .....	<ul style="list-style-type: none"> <li>—Product quantity (e.g., 20 g).</li> <li>—Portion count (e.g., 10 bits).</li> <li>—Portion mass (e.g., 2 g/bit).</li> <li>—Portion length (e.g., 8 mm, 10 mm).</li> <li>—Portion width (e.g., 6 mm, 8 mm).</li> <li>—Portion thickness (e.g., 5 mm, 7 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Other .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple smokeless tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.</li> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
	Open E-Liquid (e.g., an e-liquid in a bottle with a removable cap).	<ul style="list-style-type: none"> <li>—Package type (e.g., bottle, box).</li> <li>—Product quantity (e.g., 1 bottle, 5 bottles).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—E-liquid volume (e.g., 10 ml).</li> <li>—Nicotine concentration (e.g., 0, 0.2 mg/ml).</li> <li>—PG/VG ratio (e.g., N/A, 0/100, 50/50).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
Cigars .....	Closed E-Liquid (e.g., a sealed cartridge for use in an e-cigarette).	<ul style="list-style-type: none"> <li>—Package type (e.g., cartridge).</li> <li>—Product quantity (e.g., 1 cartridge, 5 cartridges).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—E-liquid volume (e.g., 10 ml).</li> <li>—Nicotine concentration (e.g., 0, 0.2 mg/ml).</li> <li>—PG/VG ratio (e.g., N/A, 0/100, 50/50).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Closed E-Cigarette (e.g., a cigalike).	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none, plastic clamshell).</li> <li>—Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—Length (e.g., 100 mm, 120 mm).</li> <li>—Diameter (e.g., 6 mm, 8 mm).</li> <li>—E-liquid volume (e.g., 2 ml, 5 ml).</li> <li>—Nicotine concentration (e.g., 0, 0.2 mg/ml).</li> <li>—PG/VG ratio (e.g., N/A, 0/100, 50/50).</li> <li>—Wattage (e.g., 100 W, 200 W).</li> <li>—Battery capacity (e.g., 100 mAh, 200 mAh).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
	Open E-Cigarette (e.g., a tank system).	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none, plastic clamshell).</li> <li>—Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—Length (e.g., 100 mm, 120 mm).</li> <li>—Diameter (e.g., 8 mm, 14 mm).</li> <li>—E-liquid volume (e.g., 2 ml, 5 ml).</li> <li>—Wattage (e.g., 100 W, 200 W).</li> <li>—Battery capacity (e.g., 100 mAh, 200 mAh).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	ENDS Component .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none, plastic clamshell).</li> <li>—Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	ENDS Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple ENDS tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.</li> </ul>
	ENDS Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
	Filtered, Sheet-Wrapped Cigar .....	<ul style="list-style-type: none"> <li>—Package type (e.g., hard pack, soft pack, clam shell).</li> <li>—Product quantity (e.g., 20 filtered cigars, 25 filtered cigars).</li> <li>—Characterizing flavor (e.g., none, menthol).</li> <li>—Length (e.g., 89 mm, 100 mm).</li> <li>—Diameter (e.g., 6 mm, 8.1 mm).</li> <li>—Ventilation (e.g., none, 10%, 25%).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Unfiltered, Sheet-Wrapped Cigar .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, film sleeve).</li> <li>—Product quantity (e.g., 1 cigar, 5 cigarillos).</li> <li>—Characterizing flavor (e.g., none, menthol).</li> <li>—Length (e.g., 100 mm, 140 mm).</li> <li>—Diameter (e.g., 8 mm, 10 mm).</li> <li>—Tip (e.g., none, wood tips, plastic tips).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Leaf-Wrapped Cigar .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, film, sleeve, none).</li> <li>—Product quantity (e.g., 1 cigar, 5 cigars).</li> <li>—Characterizing flavor (e.g., none, whiskey).</li> <li>—Length (e.g., 150 mm, 200 mm).</li> <li>—Diameter (e.g., 8 mm, 10 mm).</li> </ul>

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	Cigar Component .....	<ul style="list-style-type: none"> <li>—Wrapper material (e.g., burley tobacco leaf, Connecticut shade grown tobacco leaf).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (e.g., box, booklet).</li> <li>—Product quantity (e.g., 10 wrappers, 20 leaves).</li> <li>—Characterizing flavor (e.g., none, menthol, cherry).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Cigar Tobacco Filler .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, pouch).</li> <li>—Product quantity (e.g., 20 g, 16 ounces).</li> <li>—Characterizing flavor (e.g., none, tobacco, menthol, cherry).</li> <li>—Tobacco cut size (e.g., 5 mm, 10 mm).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Cigar Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple cigar tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.</li> </ul>
	Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
Pipe Tobacco Products .....	Pipe .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none).</li> <li>—Product quantity (e.g., 1 pipe).</li> <li>—Length (e.g., 200 mm, 300 mm).</li> <li>—Diameter (e.g., 25 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Pipe Tobacco Filler .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, pouch).</li> <li>—Product quantity (e.g., 20 g, 16 ounces).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, Cavendish, cherry).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Pipe Component .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bowl, shank, stem, screen, filter).</li> <li>—Product quantity (e.g., 1 bowl, 1 stem, 100 filters).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Pipe Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple pipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.</li> </ul>
	Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
Waterpipe Tobacco Products .....	Waterpipe .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none).</li> <li>—Product quantity (e.g., 1 waterpipe).</li> <li>—Length (e.g., 200 mm, 500 mm).</li> <li>—Width (e.g., 100 mm, 300 mm).</li> <li>—Number of hoses (e.g., 1, 2, 4).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Waterpipe Tobacco Filler .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, pouch).</li> <li>—Product quantity (e.g., 20 g, 16 ounces).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, apple).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	Waterpipe Heat Source .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, film sleeve, bag, none).</li> <li>—Product quantity (e.g., 150 g, 680 g).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, apple).</li> <li>—Portion count (e.g., 20 fingers, 10 discs, 1 base).</li> <li>—Portion mass (e.g., 15 g/finger).</li> <li>—Portion length (e.g., 40 mm, 100 mm).</li> <li>—Portion width (e.g., 10 mm, 40 mm).</li> <li>—Portion thickness (e.g., 10 mm, 40 mm).</li> <li>—Source of energy (e.g., charcoal, battery, electrical).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	Waterpipe Component .....	—Package type (e.g., bag, box, none). —Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (e.g., none, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Waterpipe Co-Package .....	—For a new co-packaged tobacco product composed of multiple waterpipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.
	Waterpipe Other .....	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other .....	Other .....	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

<sup>7</sup> Characterizing flavors may include those added to certain components or parts (e.g., paper) of the tobacco product. If there is no characterizing flavor, the application must state “none.”

The applicant would be required to include any additional properties needed to uniquely identify the tobacco product, if applicable (e.g., use of product descriptors such as “premium” would be required to be identified). Proposed § 1107.18(c)(8) would also require the address of the facilities involved in the manufacture of the tobacco products and any Facility Establishment Identifier number. This information would assist the Agency in making environmental impact considerations and determinations under part 25 by helping FDA understand the scale of products that would be manufactured.

d. *Summary.* Proposed § 1107.18(d) would require a summary at the beginning of the SE Report. This summary portion of the SE Report would act as an abstract designed to orient reviewers to the contents of the SE Report. Under proposed § 1107.18(d), the summary would be required to include three elements. First, the summary would be required to include a concise description of the characteristics of the new tobacco product. As stated in section 910(a)(3)(B) of the FD&C Act, characteristics means “the materials, ingredients, design, composition, heating source, or other features of a tobacco product,” all of which are defined in proposed § 1107.12. Second, the summary would also be required to include the applicant’s basis for whether the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics from the predicate tobacco product which the applicant believes do not cause the new tobacco

product to raise different questions of public health. Third, with respect to those characteristics, the summary would be required to include a description of the similarities and differences between the new tobacco product and the predicate tobacco product.

e. *New tobacco product description.* Proposed § 1107.18(e) sets forth the information that would be required in the description of the new tobacco product. Based on our experience reviewing SE Reports, FDA has found that, to have a meaningful scientific comparison, a new tobacco product should be compared to a single predicate product (this is discussed in more detail at proposed § 1107.18(f), the section of this document describing the predicate tobacco description). Accordingly, proposed § 1107.18(e) would require the applicant to identify the new tobacco product in the SE Report for comparison to one predicate tobacco product. As is currently the practice, applicants may continue to bundle groups of SE Reports submitted under proposed § 1107.18 that have the same proposed modifications (e.g., a change in ingredient supplier that results in a new tobacco product). As discussed previously, co-packaging two or more tobacco products may result in a new tobacco product.

Proposed § 1107.18(e) would require that the SE Report describe the new tobacco product in sufficient detail to enable FDA to understand and evaluate the characteristics of the new tobacco product in comparison to the predicate. Specifically, the Agency proposes that this section of the SE Report include the following information:

- A narrative description of the new tobacco product, as well as detailed drawings or schematics. The drawings would be required to identify the container closure system and illustrate all of the product’s components. As defined in proposed § 1107.12, a “component or part” of a tobacco product is any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product’s performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. The definition excludes anything that is an accessory of a tobacco product. For example, an applicant submitting an SE Report for a pouched snus product would illustrate all the components and parts of the product, including the pouch material and tobacco filler. The narrative description would identify all the components, e.g., for a cigarette, the applicant would identify the rod, and the rod’s paper and filler, and so on.
- A description of and the function for each component or part of the new tobacco product as well as an explanation of how each component or part is integrated into the product design.
- If the manufacturing process for the new tobacco product could affect the characteristics of the new product, an applicant would be required to provide an overview of the manufacturing process. This overview would not need to be an exhaustive discussion but enough information to enable FDA to fully understand and compare the characteristics that can be affected by the manufacturing process of the new

tobacco product and the predicate tobacco product. FDA has found during reviews of SE Reports that changes in manufacturing, including fermentation, may impact the characteristics of the tobacco product, *e.g.*, the quantities of nicotine (total and free), as well as HPHCs such as tobacco-specific N-nitrosamines (TSNAs). Such changes could cause the new product to raise different questions of public health, *e.g.*, fermentation can increase the levels of nicotine, which impacts dependence and cessation (Refs. 36 and 37), and an increase in TSNAs may increase the risk for certain types of cancer (Ref. 38). Thus, if fermentation is used in the manufacturing process for the new tobacco product, then the SE Report would be required to describe the process, including the type and quantity of the microbial inoculum and/or fermentation solutions (fermentation is typically used in smokeless tobacco products, and the hot and sticky environment associated with fermentation may contribute to bacteria and growth of contaminants, which is a major health and safety concern). If the manufacturing process for the new tobacco product does not affect the characteristics of the new product beyond what is described elsewhere in the SE Report, an applicant would be required to state that to satisfy this provision.

f. *Description of the predicate tobacco product.* Under proposed § 1107.18(f), the SE Report would be required to include a section describing the predicate tobacco product. Under proposed § 1107.18(f)(1), the applicant would be required to identify one predicate tobacco product that is either a grandfathered tobacco product or a tobacco product that FDA previously found to be substantially equivalent to a predicate tobacco product. The applicant may reference the STN if FDA has already made a grandfathered determination, or provide specific information sufficient to support a grandfathered determination (see the final guidance entitled “Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007” (79 FR 58358, September 29, 2014)). If the SE Report includes information to demonstrate the grandfathered status of the predicate product, FDA intends to make the grandfathered determination on that predicate tobacco product before beginning substantive scientific review of the SE Report.

As with any new tobacco product, applicants who wish to use the SE pathway to obtain marketing authorization for new co-packaged

products would have to identify a single predicate tobacco product for each new tobacco product. An applicant could use a co-packaged product as a predicate so long as it is a valid predicate; however, an applicant would not be required to use a co-packaged product as its predicate tobacco product.

FDA invites comments on this approach or any recommended alternative approaches for co-packaged products.

Proposed § 1107.18(f)(2)(i) would require that the predicate tobacco product chosen by the applicant be in the same category (*e.g.*, cigarette, smokeless) and subcategory (*e.g.*, filtered, non-filtered) as the new tobacco product to provide a meaningful starting point for our substantial equivalence review. This proposed requirement reflects FDA’s experience, which has been that if the predicate and new tobacco products differ on these points, it is highly unlikely that we would be able to find that the SE Report demonstrates the substantial equivalence of the new tobacco product to the predicate tobacco product. For example, when an SE Report includes a predicate and new tobacco product that are in different categories (*e.g.*, a comparison of a combusted tobacco product to a smokeless product), the considerable differences between the products in almost every characteristic will raise different questions of public health (*e.g.*, an applicant attempting to compare a smokeless moist snuff predicate to a new combusted filtered cigarette would likely not be able to demonstrate that the cigarette does not raise different questions of public health as compared to the smokeless moist snuff, as the properties and characteristics of the two products are so vastly different. For example, an applicant would not be able to show that a ventilation of 25 percent would not cause the cigarette to raise different questions of public health given that the smokeless moist snuff has no ventilation characteristic with which to compare). These drastic differences in characteristics make it very hard for applicants to provide the evidence necessary to show that these differences do not cause the new product to raise different questions of public health because addressing the uncertainty in the influence on adverse health impact on the user, product use, initiation, and cessation would often require complex clinical studies.

In addition, under proposed § 1107.18(f)(2)(ii), the predicate must have been either commercially marketed (not exclusively in a test market) in the United States as of February 15, 2007 (a

grandfathered predicate tobacco product), or have been previously determined to be substantially equivalent by FDA. If the SE Report is using a grandfathered predicate tobacco product, the SE Report must include a statement that “I, (name of responsible official), confirm that the predicate tobacco product, (insert name of predicate tobacco product), was commercially marketed other than for test marketing as of February 15, 2007” or reference the STN for a previous determination by FDA that the predicate tobacco product is grandfathered. The statement would be a means of ensuring that the applicant understands that the product must have been commercially marketed on February 15, 2007, to be considered grandfathered, and supports the information provided in proposed § 1107.18(f)(1).

Under proposed § 1107.18(f)(2)(iii), the applicant would be required to identify a predicate tobacco product that is an individual product. As previously discussed, an applicant could use a co-packaged product as a predicate so long as it is a valid predicate (*e.g.*, on the market as of February 15, 2007, or one that was previously found SE). However, a predicate could not be a fictional product made up by combining characteristics of two or more products that are grandfathered or have been found SE. In addition, under proposed § 1107.18(f)(2)(iv) and (v), the predicate tobacco product could not be the subject of a rescission order by FDA as described in proposed § 1107.50 and could not have been removed from the market at the initiative of FDA or have been determined by judicial order to be adulterated or misbranded. These proposed requirements are intended to minimize some of the problems with predicate tobacco products that FDA has identified during SE Report reviews which prevent us from proceeding with an SE review.

g. *Comparison information.* Proposed § 1107.18(g) states that the SE Report would be required to include a comparison of the characteristics of the new tobacco product and the predicate tobacco product, as described in proposed § 1107.19. FDA expects this comparison to be a significant part of an SE Report as it would be expected to describe in detail how the product characteristics of the new tobacco product compare to the product characteristics of the predicate tobacco product.<sup>8</sup> If the new tobacco product

<sup>8</sup> FDA notes that some applications may use surrogate tobacco products for discrete parts of an SE application. A surrogate is a tobacco product for which an applicant provides data it would like to

has some characteristics that are not identical to the predicate, but some characteristics that are identical, the applicant must provide comparison information related to the characteristics that are not identical, but may certify that the other characteristics are identical under proposed § 1107.18(l)(2).

For example, if the modification between the new and predicate product is a change to fire standard compliant (FSC) paper, the SE Report would state and provide comparison information on the difference of the non-FSC to FSC paper, the change in filtration (*e.g.*, if there is a change in filtration due to the change made to the paper), and the change in tobacco blend (*e.g.*, if there is a change in blend made with the change to the paper), but the SE Report could then include a certification that all other characteristics of the new and predicate product, other than the modified paper, filtration, and blend, are identical.

Another example is a change in product quantity (*e.g.*, an increase from 20 grams to 35 grams of loose moist snuff). In this scenario, if the per weight composition has not changed, the applicant could provide comparison information on only the characteristics that differ between the new and predicate product, and include a certification under proposed § 1107.18(l)(2) that all other characteristics are identical. A third example would be a container closure system (CCS) substitution of a bag for a box. In this case, the SE Report would provide comparison information on the change in CCS and the SE Report could then include a certification under proposed § 1107.18(l)(2) that the characteristics of all non-CCS items have not changed (*e.g.*, rolling papers are identical between the new and predicate product). The applicant would be required to maintain records supporting the certification consistent with proposed § 1107.58.

*h. Comparative testing information.* Other than for characteristics that are

identical (and for which the applicant has certified that the characteristics are identical under paragraph (l)(2)), proposed § 1107.18(h) would require the SE Report to include testing information on the characteristics of the new and predicate tobacco products as described in section § 1107.19, except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product: (1) Has the same characteristics as the predicate or (2) does not raise different questions of public health. For example, it may not always be necessary to provide comparative testing information on the heating source.

Comparative testing supports the SE Report by showing the information contained in the SE Report is meaningful and accurate and, where applicable, helps demonstrate that the different characteristic(s) in a new tobacco product does not raise different questions of public health. FDA's experience has been that the summary data provided in some SE Reports has been miscalculated, and thus, a substantial equivalence determination was not supportable. To ensure the accuracy of the data provided, FDA has needed to review the experimental data.

Accordingly, proposed § 1107.18(h)(1) would require that the SE Report include test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results). Under proposed § 1107.18(h)(2), the testing would be required to be conducted on a sufficient sample size and on samples that reflect the final tobacco product composition and design. Proposed § 1107.18(h)(3) would require the SE Report to state whether the testing method for the new and predicate products are the same and, if they differ, to explain how the results of the different test methods can be compared. Under proposed § 1107.18(h)(4), the SE Report also must identify any national and international standards used to test the new and predicate tobacco products and explain any deviations.<sup>9</sup> If no standards were used for testing, the SE Report would be required to state so. There are multiple ways to satisfy this comparative testing requirement that may not require comparative testing on the specific characteristic that is different between the new and predicate tobacco product. For example, if an applicant is proposing to modify the container

closure system of a smokeless tobacco product for loose moist snuff, rather than supply testing information on the container closure system, the applicant could demonstrate that the ingredients, constituents, moisture, and stability of the loose tobacco within the container closure system are not affected by the change in container closure system in a way that would cause the new product to raise different questions of public health. As testing information on the ingredients, constituents, moisture, and stability information would already be required for the smokeless tobacco product, additional comparative testing information on differences in the container closure system would not be required. Instead the applicant would state that this information is already covered by the submission of the ingredients, constituents, moisture, and stability information within the SE Report.

*i. Statement of compliance with applicable tobacco product standards.* As required by section 905(j)(1)(B) of the FD&C Act, under proposed § 1107.18(i), the SE Report must list and describe the action(s) that the applicant has taken to comply with the requirements under section 907 of the FD&C Act (tobacco product standards) that are applicable to the tobacco product. In the alternative, the SE Report must state that there are no requirements under section 907 that are applicable to the new tobacco product. For SE Reports that are submitted after the finalization of this rule, but still pending after issuance of any future tobacco product standards, FDA invites public comments on how such pending SE Reports should be considered or handled in relation to the satisfaction of the requirement for a statement of compliance with applicable tobacco product standards.

*j. Health information summary or statement regarding availability of such information.* As required by section 910(a)(4) of the FD&C Act, the SE Report must include either an adequate summary of any health information related to the new tobacco product or a statement that such information would be made available upon request by any person. Proposed § 1107.18(j) would codify this statutory requirement and ensure that applicants provide adequate information as required by section 910(a)(4). Under proposed § 1107.18(j)(1), if the applicant chooses to provide a health information summary, the applicant would be required to provide a redacted version of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and

extrapolate to the new, predicate tobacco product or both new and predicate tobacco products. However, the surrogate tobacco product is neither the new or predicate tobacco product (a grandfathered determination is not necessary for surrogate tobacco products as it is not a predicate tobacco product). Data for a surrogate tobacco product is provided in place of data or to provide a bridge between data for the new or predicate tobacco product. A surrogate tobacco product is used when there is inadequate data available for the new or predicate tobacco product; data for a surrogate tobacco product supplement the data for a new or predicate tobacco product. Unlike predicate tobacco products, surrogate tobacco product data may be in place at the start of substantive scientific review or may be provided in response to a deficiency letter. FDA invites comments on the use of surrogate tobacco products.

<sup>9</sup> In the guidance document entitled, "Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" (January 2011), FDA provided some examples of standards that might be used to support an SE application.

20.63 (21 CFR 20.61 and 20.63). FDA believes that an SE Report redacted in the manner described would generally provide an adequate summary of any health information related to the new tobacco product, as well as detailed information regarding data concerning adverse health effects of the new tobacco product. The redacted SE Report would be required to be submitted with the original submission, and a redacted copy of an amendment would be required with the submission of any amendment to the SE Report.

In addition, to the extent that there is additional health information about the new tobacco product, including any information, research (*e.g.*, published or unpublished research, internal reports or analyses), or data about adverse health effects, that the applicant has or knows about and that is not contained in the SE Report, the applicant would be required to provide such accurate and complete, and not false or misleading, information in the health information summary. If there is no such additional health information, the SE Report would be required to include a statement that the company does not have and does not know of any such additional health information. FDA would post the health information summary, including the redacted SE Report, and any additional health information provided by the applicant on FDA's website.

Under proposed § 1107.18(j)(2), if the applicant chooses to make the health information available upon request, the SE Report would be required to include a certification statement made by an authorized representative of the applicant that an adequate summary of any health information related to the new tobacco product, including detailed information regarding data concerning adverse health effects of the new tobacco product, would be made available to a requestor within 30 calendar days of a request. The certification is intended to ensure that applicants understand that they are responsible for providing this information upon request.

Under proposed § 1107.18(j)(3), the health information the applicant would need to make available would be a copy of the full SE Report (which includes any amendments), excluding research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63. To the extent that the applicant has or knows of any additional health information, including any information, research, or data regarding adverse health effects that is not contained in the SE Report, the applicant would also provide the requester such accurate and complete,

and not false or misleading, information. If there is no such additional health information, the applicant would provide the requester with a statement that the company does not have and does not know of any such additional health information.

Proposed § 1107.18(j)(4) would provide that requests for health information be made to the authorized representative of the applicant, whose contact information the applicant would provide to FDA. FDA intends to make this contact information available on FDA's website. The applicant would be required to update this contact information with FDA whenever necessary (*e.g.*, the identified authorized representative is no longer with the company or the address or telephone information changes). If an applicant elects to include the statement in their SE Report, the applicant would be required to provide the information to persons who request it. Applicants would not be permitted to later amend SE Reports on which FDA has issued a marketing order to choose instead to submit a health information summary. Therefore, applicants that provide the statement instead of providing the summary to FDA as part of the SE Report must be prepared to provide the information required under section 910(a)(4) of the FD&C Act, as implemented through proposed § 1107.18(j).

Under proposed § 1107.18(j)(5), to the extent information is included in the health information summary or the health information provided upon request under paragraphs (j)(1) and (2) of this section that is not required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act or paragraph (j) of this section, that information cannot contain a statement that would cause the proposed new tobacco product to be in violation of section 911 of the FD&C Act (21 U.S.C. 387k) upon the introduction or delivery for introduction of the proposed new product into interstate commerce. If an applicant includes such a statement in its health information summary or in the health information the applicant provides upon request, the review of the applicant's SE Report may be delayed.

FDA would generally not consider a statement of relative risk to be required by section 910(a)(4) of the FD&C Act or paragraph (j) of this section if the risk being conveyed is unrelated to the applicant's demonstration that the new product is substantially equivalent and FDA's review of the SE Report. For example, if an applicant submitted an SE Report for a new smokeless tobacco product and identified a smokeless

tobacco product as the predicate product, a statement comparing the tar in the new smokeless tobacco product to the tar in a cigarette would generally be unrelated to the applicant's demonstration that the new product is substantially equivalent and FDA's review of the SE Report.

For the purposes of § 1107.18(j), any statement an applicant is required to include in a health information summary or the health information provided in response to a request—including statements made in an SE Report (*e.g.*, comparisons of HPHCs between the new and predicate tobacco products)—typically would not cause the proposed new tobacco product to be in violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the proposed new product into interstate commerce. Congress required applicants to submit health information summaries with their SE Reports or to provide such information upon request. Nothing in section 911 of the FD&C Act suggests that Congress intended for that provision to impede an applicant's ability to fulfill its obligations under section 910(a)(4) of the FD&C Act.

k. *Compliance with part 25.* An applicant must include an environmental assessment (EA) prepared in accordance with § 25.40 or a valid claim of a categorical exclusion, if applicable. (Under § 25.15(a), all submissions requesting FDA action require the submission of either a claim of categorical exclusion or an EA.) In accordance with § 25.40(a), an environmental assessment must include, at a minimum, brief discussions of the need for the proposed action, of alternatives as required by section 102(2)(E) of the National Environmental Policy Act (NEPA), of the environmental impacts of the proposed action and alternatives, a listing of the agencies and persons consulted, and the relevant environmental issues relating to the use and disposal from use. Although applicants may wish to review the categorical exclusions specific to tobacco product applications at § 25.35, the only categorical exclusion currently available for an order authorizing the marketing of a new tobacco product is found at § 25.35(a), and applies only to orders finding provisional products substantially equivalent. If the applicant believes the action would qualify for an available categorical exclusion, the applicant would be required to state under § 25.15(a) and (d) that the action qualifies for a categorical exclusion, cite to the claimed exclusion, and state that to the applicant's knowledge no

extraordinary circumstances exist under § 25.21.

To evaluate the environmental impact (as described in § 25.40(a)), information that addresses the status of the new tobacco product relative to the predicate tobacco product would be required. Accordingly, the environmental assessment would be required to include a statement indicating whether the new tobacco product is intended to: (1) Replace the predicate tobacco product once the new tobacco product receives market authorization and is commercially marketed; (2) be a line extension of the predicate tobacco product; (3) be marketed along with the predicate product by the same manufacturer; and/or (4) be marketed along with the predicate tobacco product by a different manufacturer (e.g., by a manufacturer other than the manufacturer of the predicate tobacco product). This statement would be included in the section on the need for the proposed action and would help FDA understand the environmental impact of an SE order by understanding the marketing intention for the new and predicate tobacco products. The marketing authorization of a new tobacco product may have a different impact if the new tobacco product is intended to be marketed along with the predicate tobacco product than if the new tobacco product is intended to replace a predicate tobacco product.

1. *Certification statement.* Proposed § 1107.18(l)(1) would require that an applicant include in the SE Report a specific statement certifying that the applicant would maintain all records to substantiate the accuracy of the report consistent with the record retention requirements in proposed § 1107.58, that, to the best of their knowledge, the information and accompanying

submission are true and correct, no material fact has been omitted, the signer is authorized to submit the information on the applicant's behalf, and that the signer understands that anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties (under 18 U.S.C. 1001). The certification is intended to provide FDA with additional assurance that the applicant has fully considered the SE Report and its contents, that the applicant believes there is a basis for making the findings required by section 910(a)(2) of the FD&C Act, and that the applicant understands the potential consequences of submitting false information to the U.S. Government.

In addition, under proposed § 1107.18(l)(2), if an SE Report states that the new tobacco product has certain characteristics that are identical to the predicate tobacco product (though not all characteristics, such that the product would not be "new"), an applicant can choose to submit a certification in lieu of providing information for each characteristic of the new and predicate tobacco products. FDA would permit the applicant to certify that the other characteristics are identical as long as the applicant maintains supporting documentation, including the records demonstrating the comparison information detailed in proposed § 1107.19. The records would be required to be maintained consistent with proposed § 1107.58. The certification must be signed by an authorized representative of the applicant.

3. Comparison Information (Proposed § 1107.19)

This proposed section describes the comparison information that would be required in the SE Report. Comparative testing supports the SE Report by showing the information contained in the SE Report is meaningful and accurate; where applicable, the testing also helps demonstrate that the different characteristic(s) in a new tobacco product does not raise different questions of public health. FDA requests public comments on the quantitative and qualitative differences in each of the design parameters for each of the tobacco product categories identified below as well as data to support such values or characteristics.

a. *Product design.* Proposed § 1107.19(a) would require the SE Report to include descriptions of the product designs of the new and predicate tobacco products and identify any differences. This proposed section would require that the information be in a tabular format with a side-by-side comparison of each design parameter of the new and predicate tobacco products. The SE report would also be required to include for each design parameter a target value and range of acceptable values, actual measured value (if applicable), and ranges of measured values (if applicable) with units of measure. The report would also be required to include test data for each applicable design parameter. Proposed § 1107.19(a)(1)-(6) would establish the required design parameter information for the tobacco product category, as follows:

For cigarettes, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 3—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Cigarette length (mm)</li> <li>—Cigarette circumference (mm)</li> <li>—Cigarette draw resistance (mm H<sup>2</sup>O)</li> <li>—Tobacco filler mass (mg)</li> <li>—Tobacco rod density (g/cubic centimeter (cm<sup>3</sup>))</li> <li>—Tobacco moisture (%)</li> <li>—Filter ventilation (%)</li> <li>—Tipping paper length (mm)</li> <li>—Cigarette paper base paper basis weight (g/meter squared(m<sup>2</sup>))</li>   <li>—Cigarette paper base paper porosity (CU)</li> <li>—Cigarette paper band porosity (CU)</li> <li>—Cigarette paper band width (mm)</li> <li>—Cigarette paper band space (mm)</li> </ul>	<ul style="list-style-type: none"> <li>—Puff count.</li> <li>—Cigarette draw resistance (mm H<sup>2</sup>O).</li> <li>—Tobacco filler mass (mg).</li> <li>—Tobacco moisture (%).</li> <li>—Filter ventilation (%).</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU).</li> <li>—Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)].</li> <li>—Filter pressure drop (mm H<sup>2</sup>O).</li> </ul>

TABLE 3—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density))</li> <li>—Filter length (mm)</li> <li>—Filter pressure drop (mm H<sup>2</sup>O)</li> </ul>	

FDA is proposing to require that these parameters be included for cigarettes because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

- A difference in cigarette length may alter tobacco biomarker levels (Ref. 5).
- A difference in cigarette circumference may affect filter efficiency and, in turn, smoke constituent yields (Ref. 6).
- A difference in puff count can directly affect smoke constituent yields (Ref. 7).
- A difference in cigarette draw resistance may result in differences in the difficulty of pulling air through the tobacco rod and, in turn, affect smoke constituent yields (Ref. 8).
- A difference in tobacco filler mass may affect smoke constituent yields (Refs. 9 and 10).
- A difference in tobacco rod density may modify burn properties and smoke constituent yields (Refs. 11 and 12).

- A difference in tobacco moisture may affect puff count (Refs. 13–15).
- A difference in cigarette paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 16).
- A difference in cigarette paper base paper porosity may affect smoke constituent yields (Ref. 16).
- A difference in cigarette paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Refs. 18, 19, and 38).
- A difference in cigarette paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 20).
- A difference in cigarette paper band space may affect ignition propensity and, in turn, puff count (Ref. 21).
- A difference in filter efficiency may affect smoke constituent yields (Refs. 18 and 20).

- A difference in denier per filament may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
  - A difference in total denier may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
  - A difference in filter density may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
  - A difference in filter pressure drop may affect smoke constituent yields (Ref. 23, slide 40).
  - A difference in filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
  - A difference in filter ventilation may affect smoke constituent yields (Ref. 6).
  - A difference in tipping paper length may affect smoke constituent yields (Ref. 24).
- For portioned and non-portioned smokeless tobacco products, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 4—REQUIRED DESIGN PARAMETER INFORMATION FOR PORTIONED AND NON-PORIONED SMOKELESS TOBACCO PRODUCTS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
Portioned Smokeless Tobacco Products	
<ul style="list-style-type: none"> <li>—Tobacco cut size (mm)</li> <li>—Tobacco moisture (%)</li> <li>—Portion length (mm) (if applicable)</li> <li>—Portion width (mm) (if applicable)</li> <li>—Portion mass (mg) (if applicable)</li> <li>—Portion thickness (mm) (if applicable).</li> <li>—Pouch paper wicking.</li> <li>—Pouch paper porosity (CU).</li> <li>—Pouch paper basis weight (g/m<sup>2</sup>).</li> </ul>	<ul style="list-style-type: none"> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> <li>—Portion mass (mg) (if applicable).</li> <li>—Pouch paper porosity (CU).</li> <li>—Pouch paper basis weight (g/m<sup>2</sup>).</li> </ul>
Non-portioned Smokeless Tobacco Products	
<ul style="list-style-type: none"> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> </ul>	<ul style="list-style-type: none"> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> </ul>

FDA is proposing to require that these parameters be included for smokeless tobacco products because variations in these parameters may cause the new tobacco product to raise different

- questions of public health, as described below:
- A difference in tobacco cut size may alter the surface area and accessibility of saliva to get to the surfaces of the tobacco, thereby affecting the amount

- and rate of constituents released from the product (Ref. 25).
- A difference in tobacco moisture may affect microbial growth in the product, extraction efficiency, and total exposure to nicotine, NNN, and NNK (Ref. 26).

- A difference in portion mass may affect user exposure to the tobacco product and, in turn, exposure to the HPHCs contained in each portion (Ref. 27).
- A difference in portion length as it relates to portion size may affect the amount of constituents in each portion (Ref. 27).
- A difference in portion width may result in a surface area difference, which is proportional to the amount and rate

- of constituents released from the product (Ref. 28).
- A difference in portion thickness may result in a surface area difference, which is directly proportional to the amount and rate of constituents released from the product (Ref. 28).
  - A difference in pouch paper basis weight may alter the interactions between the tobacco and oral cavity, thereby affecting the amount and rate of

- constituents released from the product (Ref. 29).
- A difference in pouch paper porosity may alter the interactions between the tobacco and oral cavity, thereby affecting the amount and rate of constituents released from the product (Ref. 29).
- For RYO tobacco rolling papers, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 5—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO ROLLING PAPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Paper length (mm).</li> <li>—Paper width (mm).</li> <li>—Mass per paper (mg).</li> <li>—Cigarette paper base paper basis weight (g/m)<sup>2</sup>.</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU) (if applicable).</li> <li>—Cigarette paper band width (mm) (if applicable).</li> <li>—Cigarette paper band space (mm) (applicable).</li> </ul>	<ul style="list-style-type: none"> <li>—Mass per paper (mg).</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU) (if applicable).</li> </ul>

FDA is proposing to require that these parameters be included for rolling papers because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

- A difference in overall length may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 23, slide 46).
- A difference in overall width may alter the surface area that is available for tobacco packing, thereby affecting the

- smoke constituent yields (Ref. 23, slide 46).
- A difference in total mass per pack may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 16 and 23 (slide 46)).
  - A difference in RYO paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 16).
  - A difference in RYO paper base paper porosity may affect smoke constituent yields (Ref. 16).
  - A difference in RYO paper band porosity may affect smoke constituent

- yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Refs. 17 and 37).
- A difference in RYO paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 20).
  - A difference in RYO paper band space may affect ignition propensity and, in turn, puff count (Ref. 21).
- For RYO tobacco tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 6—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Tube length (mm).</li> <li>—Tube circumference (mm).</li> <li>—Total mass (mg).</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU).</li> <li>—Cigarette paper band width (mm).</li> <li>—Cigarette paper band space (mm).</li> </ul>	<ul style="list-style-type: none"> <li>—Total mass (mg).</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU).</li> </ul>

For RYO tobacco filtered tubes, the required design parameter information

to be provided for each new predicate and new tobacco product would be:

TABLE 7—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Tube length (mm).</li> <li>—Tube circumference (mm).</li> <li>—Total mass (mg).</li> <li>—Tipping paper length (mm).</li> </ul>	<ul style="list-style-type: none"> <li>—Total mass (mg).</li> <li>—Filter ventilation (%).</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>).</li> <li>—Cigarette paper base paper porosity (CU).</li> </ul>

TABLE 7—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Filter ventilation (%).</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU).</li> <li>—Cigarette paper band width (mm).</li> <li>—Cigarette paper band space (mm).</li> <li>—Filter length (mm).</li> <li>—Filter denier per filament (DPF).</li> <li>—Filter total denier (g/9000m).</li> <li>—Filter density (g/cm<sup>3</sup>).</li> <li>—Filter pressure drop (mm H<sub>2</sub>O).</li> </ul>	<ul style="list-style-type: none"> <li>—Cigarette paper band porosity (CU).</li> <li>—Filter denier per filament (DPF).</li> <li>—Filter total denier (g/9000m).</li> <li>—Filter density (g/cm<sup>3</sup>).</li> <li>—Filter pressure drop (mm H<sub>2</sub>O).</li> </ul>

FDA is proposing to require that these parameters be included for RYO tobacco tubes because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

- A difference in tube length may alter tobacco biomarker levels (Ref. 5).
- A difference in tube circumference may affect filter efficiency and, in turn, smoke constituent yields (Ref. 6).
- A difference in total mass per pack may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 16 and 23 (slide 46)).
- A difference in tube paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 16).

- A difference in tube paper base paper porosity may affect smoke constituent yields (Ref. 16).
- A difference in tube paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Refs. 17 and 37).
- A difference in tube paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 20).
- A difference in tube paper band space may affect ignition propensity and, in turn, puff count (Ref. 21).
- A difference in filter efficiency may affect smoke constituent yields (Ref. 13).
- A difference in denier per filament may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).

- A difference in total denier may affect filter efficiency and, in turn, smoke constituent yields (Ref. 33).
  - A difference in filter density may affect filter efficiency and, in turn, smoke constituent yields (Ref. 32).
  - A difference in filter pressure drop may affect smoke constituent yields (Ref. 23, slide 40).
  - A difference in filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 32).
  - A difference in ventilation may affect smoke constituent yields (Ref. 24).
  - A difference in tipping paper length may affect smoke constituent yields (Ref. 24).
- For RYO tobacco, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 8—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Tobacco filler mass (mg).</li> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> </ul>	<ul style="list-style-type: none"> <li>—Tobacco filler mass (mg).</li> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> </ul>

FDA is proposing to require that these RYO tobacco parameters be included for RYO tobacco because variations in these parameters may cause the new tobacco products to raise different questions of public health, as described below:

- A difference in tobacco filler mass may affect smoke constituent yields when used with rolling paper (Ref. 9).
- A difference in tobacco cut width alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 30).
- A difference in moisture may affect smoke composition (Ref. 13).

For tobacco products not specifically identified (e.g., ENDS, cigars) FDA invites comments and information on the parameters that may be needed to support an SE Report.

b. *Heating source.* Proposed § 1107.19(b) would require that the SE Report include a description of any heating source for both the new and predicate tobacco products (e.g., burning coal, electric, chemical reaction, carbon tip) and identify any differences. If there is no heating source for the new and predicate tobacco products, the SE Report would be required to state that.

c. *Product composition.* Proposed § 1107.19(c) would require that the SE Report include descriptions of the product composition of the new and predicate tobacco products and identify any differences. The information would be required to be in tabular format with a side-by-side comparison of the materials and ingredients for each

component or part of the new and predicate tobacco products. Under the proposed rule, the SE Report would be required to provide for each material and ingredient the following information: The quantity, the target value and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part.

Proposed § 1107.19(c)(1) would require that the SE Report include the following information for each material in the product:

- The material name and common name (if applicable);
- The component or part where it is located;

- The subcomponent or subpart where it is located (if applicable);
- The function of the material;
- Quantities (including ranges or means and acceptance limits) with identification of any specification variation between the new tobacco product and predicate tobacco product;
- Specifications (including quality, grades, and suppliers) used for the new tobacco product and the predicate (including any specification variations, if applicable); and

- Any other material properties necessary to characterize the new and predicate tobacco products.

Proposed § 1107.19(c)(2) would require that the SE Report include information on ingredients other than tobacco (information on tobacco ingredients is addressed in proposed § 1107.19(c)(3)). Required information would include:

- International Union of Pure and Applied Chemistry chemical name and common name (if applicable);
- Chemical Abstracts Service (CAS) number(s) or FDA Unique Ingredients Identifier;

- The function of the ingredient;
- The quantity with the unit of measure (including ranges or means, and acceptance limits) of the materials in the new tobacco product and predicate tobacco product (with any specification variation, if applicable);

- The specifications (including purity or grade and supplier);
- For complex purchased ingredients, each single chemical substance reported separately; and

- Any other ingredient information necessary to characterize the new and predicate tobacco products.

Proposed § 1107.19(c)(3) would require information on tobacco ingredients. This information would include the following:

- The type of tobacco, including grade and variety. This impacts the characteristics of the products because different grades have different constituent profiles (the SE Report would need to include information on the applicant's grading system so that FDA understands the grade);

- The quantity, with the unit of measure (including ranges or means, and acceptance limits), of tobacco in the new and predicate tobacco products (with a specification variation, if applicable);

- The specification of tobacco used for the new tobacco product and predicate tobacco product (with any specific variation, if applicable);

- A description of any genetic engineering that impacts characteristics, because genetic engineering affects the constituent profile; and

- Any other information about tobacco ingredients necessary to characterize the new and predicate tobacco products.

If the new tobacco product does not contain tobacco (e.g., rolling paper or tipping paper), this section of the report would be required to state that.

FDA is proposing that ingredient quantities under proposed § 1107.19(c)(2) and (3) be reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products. These specific measurements provide consistent, complete information that would allow FDA to understand the ingredient quantities. In contrast, if ingredient quantities were reported as percentages, FDA would have to make assumptions about the denominator used to calculate the percentage. For example, if xylitol were reported as 10 percent of a portioned moist snuff, FDA would not be able to determine if xylitol was 10 percent of the mass of the tobacco filler or of the entire product (containing filler, paper, etc.).

Proposed § 1107.19(c)(4) would require that the SE Report include a description of the container closure system for the new and predicate tobacco products, including a side-by-side quantitative comparison of the subcomponents or subparts and materials and annotated illustrations.

d. *Other features.* Proposed § 1107.19(d) would require that the SE Report include descriptions of any other applicable features of the new and predicate tobacco products and identify any differences that exist. If a specific feature described in proposed § 1107.19(d) is not applicable to the new tobacco product, the SE Report would be required to state as such. In response, FDA may request a scientific explanation for why a particular feature is not applicable, and under proposed § 1107.19(d) the applicant would be required to provide that information to FDA. The SE Report must also address any other product characteristics that relate to the chemical, physical or biological properties of the tobacco product and are necessary for SE Report review.

Specifically, proposed § 1107.19(d)(1) would require that the SE Report include HPHC and other constituent information as appropriate to demonstrate that: (1) The new tobacco product has the same characteristics as the predicate tobacco product or (2) any differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product

to raise different questions of public health, as follows:

- Constituent names in alphabetical order,
- Common names,
- CAS number,
- Mean quantity and variance with unit of measure,
- Number of samples and measurement replicates for each sample,
- Analytical methods used, description and associated reference(s),
- Testing laboratory(ies) and accreditation information,
- Length of time between dates of manufacture and dates of testing,
- Storage conditions of the tobacco product before it was tested, and
- Full test data (including test protocols, any deviations from the test protocols, quantitative acceptance (pass/fail) criteria, and complete data sets) for all testing performed.

For combusted tobacco products, constituent smoke yields from the new and predicate products would need to be determined using intense and non-intense smoking regimens.<sup>10</sup> Two smoking regimens are required in order to understand the way that constituent yields delivered by a tobacco product can change over a range of different smoking conditions. If constituent yields were only reported from a single smoking regimen, FDA would have limited and potentially misleading information about constituent yields produced by a given tobacco product. Many studies demonstrate that different smoking regimens result in different constituent yields from the same product (Refs. 31 and 32). By requiring both an intense and a non-intense smoking regimen, FDA would have a better understanding of quantities of each constituent that may be produced by the tobacco product when smoked under different conditions. If an alternative to these smoking regimens is used, the applicant would be required to provide an explanation of why the alternative provides comparable results to the intense and non-intense smoking regimens.

FDA is proposing that the HPHC information in an SE Report for a new cigarette include, at a minimum, a comparison of the quantities of nicotine-dry particulate matter, total particulate matter, carbon monoxide, and nicotine (total) in the mainstream smoke of the new tobacco product with that of the predicate tobacco product, using both intense and non-intense smoking regimens. Further, additional HPHC

<sup>10</sup> These refer to regimens by the International Organization for Standardization and Health Canada.

yields may need to be reported in order to demonstrate that: (1) The new tobacco product has the same characteristics as the predicate tobacco product or (2) any differences in characteristics do not cause the new tobacco product to raise different questions of public health. For example, blend differences may require reporting of HPHC yields specific to the differences in tobacco blends. Studies show that the mainstream smoke of burley and reconstituted tobaccos contains much higher TSNA levels than the mainstream smoke of bright and oriental tobacco, whereas the mainstream smoke of bright tobacco contains higher benzo[a]pyrene levels than other tobacco types (Refs. 33 and 34). Reconstituted tobacco can produce high levels of carbon monoxide, nitrogen oxides, and TSNA during combustion (Ref. 8). Smoke from cigarettes made from expanded stems is higher in carbon monoxide, nitrous oxides, formaldehyde, tar, benzo[a]anthracene, and benzo[a]pyrene than smoke from cigarettes made of puffed tobacco, expanded tobacco, or freeze-dried tobacco (Ref. 30). Similarly, addition of sugar or corn syrup to a tobacco product may increase HPHCs such as formaldehyde and may therefore require additional HPHC measurements (Ref. 35). Or, if the new tobacco product contains significantly more guar gum (a binder in rod paper and tobacco blends) than the predicate product, additional HPHC yields may be required to be reported because pyrolysis of guar gum may form formaldehyde, acetaldehyde, acetone, benzene, cresol, and toluene (Refs. 39–41).

Based on its experience reviewing new tobacco products, FDA has found significant increases in HPHCs (e.g., TSNA and polycyclic aromatic hydrocarbons (PAHs)) in cigarettes due to changes in types of tobacco when compared to a predicate tobacco product. For all new cigarettes that have a substantial increase in other types of tobacco, to support a finding of SE the applicant should include a comparison of TSNA and PAHs in the mainstream smoke of the new tobacco product with that of the predicate tobacco product using both intense and non-intense smoking regimens. Depending on the specific differences between the new and predicate products, quantities of additional HPHCs in mainstream smoke may be required to be reported.

For a smokeless tobacco product, the HPHC information in an SE Report would need to include a comparison of the quantities of total and free nicotine, total TSNA, NNN, and NNK in the tobacco of the products. Depending on

the specific differences between the new and predicate products, the applicant may be required to report quantities of additional HPHCs in the product.

Proposed § 1107.19(d)(2) would require that the SE Report include a description and comparison of any other features of the new and predicate tobacco products.

Proposed § 1107.19(e) would require stability information for smokeless tobacco products and any tobacco product that contains fermented tobacco. As described in more detail in the following paragraphs, stability information is a particular concern with smokeless tobacco products and other tobacco products that contain fermented tobacco because the characteristics of these products can be affected by the manufacturing process, storage conditions, and length of time on a shelf. Accordingly, proposed § 1107.19(e) would require stability information for the new and predicate tobacco products, including:

- A description of how stability is indicated and whether stability testing is identical for the predicate and new tobacco products (proposed § 1107.19(e)(i));
- Any known or expected impacts on product stability due to differences between the new and predicate products (if there are none, the SE Report would state that) (proposed § 1107.19(e)(ii)). For example, for products that contain fermented tobacco, the SE Report would be required to provide information on the fermentation processing steps, including the following:
  - Composition of the inoculum including species name(s) and concentration(s)
  - pH
  - Temperature
  - Moisture content
  - Water activity
  - Duration
  - Ingredients added.

FDA is proposing to require that this information be submitted in the SE Report because these parameters of the fermentation process can result in different degrees of change in the chemical constituents of the tobacco (Refs. 42 and 43) and affect the type and amount of microorganisms in the final product (Ref. 44), thereby affecting the stability of the product, which could change the characteristics of the tobacco product, which may cause the new tobacco product to raise different questions of public health. In addition, the type and amount of the fermentation inoculum can be used to control or affect the fermentation process and thus, can change the product as a result of

directed fermentation, which could cause the new tobacco product to raise different questions of public health (Ref. 45).

• Detailed stability testing information, including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all stability testing performed (proposed § 1107.19(e)(iii)). Stability testing would be required to be performed at the beginning (zero time), middle, and end of the expected storage time for the following chemical and microbial endpoints:

- Microbial content data, including total aerobic microbial count and total yeast and mold count, along with identification of detected microbiological organisms by genus and species names (if applicable)
- pH
- Moisture content
- Water activity
- Tobacco-specific nitrosamines (TSNAs, including total, NNN, and NNK)
- Nitrate and nitrite levels
- Preservatives and microbial metabolic inhibitors, if any
- Method of heat treatment or pasteurization used to reduce microbial loads.

The proposed rule would require this information because product stability is affected by factors such as the fermentation and stabilization processes (if applicable), addition of chemical additives to control microbial activity (e.g., preservatives, metabolic inhibitors, humectants), and water activity ( $a_w$ ) of the product (Refs. 42, 46–48). Additionally, factors such as nitrate/nitrite concentrations, moisture content, microbial content, storage temperature, and pH are reported to influence the microbial stability and TSNA formation during storage of tobacco products (Refs. 49–53).

• Storage conditions for samples retained for testing, identifying the test methods used, along with testing of the tobacco product in the same container closure system as that in which the tobacco product is intended to be marketed, and testing supporting the expiration date (proposed § 1107.19(e)(iv)). Accelerated studies, combined with basic stability information, could be used to support tentative expiration dates provided full shelf life studies are not yet available but are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, stability studies would need to be conducted to support the SE

Report, including tobacco product testing at appropriate intervals, until the tentative expiration date could be verified or the appropriate expiration date could be determined.

Proposed § 1107.19(e)(v) and (vi) would require information on the stability testing laboratory and identification of the microbiological organisms by genus and species names, where applicable, along with the culture collection number either used during the manufacturing process and/or detected through stability testing.

Proposed § 1107.19(f) would require applicants to state that the new tobacco product has either: (1) The same characteristics as the predicate tobacco product and the basis for this determination or (2) different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (see § 1107.19(a)); heating source (see § 1107.19(b)); materials and ingredients (see § 1107.19(c)); and other features (see § 1107.19(d)). In addition, in order to demonstrate that a new tobacco product with different characteristics is substantially equivalent, an applicant must also explain why any differences in the manufacturing process that could affect the characteristics of the new product do not cause the new product to raise different questions of public health (see § 1107.18(e)). Similarly, for smokeless tobacco products, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not raise different questions of public health (see § 1107.19(e)).

Proposed § 1107.19(g) would explain that, if the applicant is comparing the new tobacco product to a predicate product that FDA has previously found to be substantially equivalent to another product, FDA may request that the applicant include information related to the original grandfathered tobacco product. Although an applicant can support a showing of SE by comparing the new tobacco product to a tobacco product that is grandfathered or that FDA has previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C

Act). This statutory provision helps FDA ensure that new tobacco products using the substantial equivalence pathway and relying on predicate tobacco products previously found SE do not vary so much from the original grandfathered tobacco product that the new product would actually raise different questions of public health compared to the originally grandfathered tobacco product. New products with differences that may appear only incremental when a new tobacco product is compared to a predicate product previously found SE may actually have had significant changes when compared to the grandfathered tobacco product.

Because the statute permits applicants to compare to either a grandfathered tobacco product or one that FDA has previously found SE (section 905(j)(1)(A)(i)) but also requires FDA to make an SE determination by comparing the new tobacco product to the grandfathered tobacco product (section 910(a)(2)(A)(i)(I)), FDA is proposing the approach in § 1107.19(g). To meet its statutory obligation, FDA may need to look back to previously submitted SE Reports in the SE chain that rely on the original grandfathered product in order to issue an SE order. Manufacturers have been on notice since the passage of the Tobacco Control Act that FDA must make the comparison between the new tobacco product and the original grandfathered tobacco product, and in doing so, may need to rely on previously submitted SE Reports, even if submitted by a different manufacturer than the applicant at hand.

Accordingly, for SE Reports that compare the new tobacco product to a predicate tobacco product that FDA previously found substantially equivalent, proposed § 1107.19(g) states that, if requested by FDA, the applicant would be required to provide information related to the original grandfathered tobacco product, even if the grandfathered tobacco product is several tobacco products removed from the predicate identified by the applicant. FDA would request this information when necessary to ensure that any order issued by the Agency complies with section 910(a)(2)(A)(i)(I) of the FD&C Act. Before requesting this information from the applicant, FDA would review other relevant SE Reports in the chain, for example, the first SE Report that received an SE order using the grandfathered product as a predicate product to make this finding. If FDA is unable to look back to data provided to the Agency regarding the grandfathered product and the applicant does not provide the information, FDA would be

unable to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act. FDA encourages applicants to provide this information with the initial SE Report to support an efficient review of the SE Report, although FDA acknowledges this may be more difficult if the applicant is not the manufacturer or owner of the predicate tobacco product. FDA requests specific public comment on this proposed provision and any challenges it may present.

#### 4. Amendments (Proposed § 1107.20)

Proposed § 1107.20(a) would permit an applicant to submit an amendment to an SE Report. Proposed § 1107.20(a) would require any applicant who chose to submit a health information summary with its SE Report under proposed § 1107.18(j)(1) to submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential and commercial information as defined in §§ 20.61 and 20.63 (21 CFR 20.61 and 20.63).

An applicant may not amend an SE Report to change the predicate tobacco product (proposed § 1107.20(b)). Because the comparison between the new and predicate tobacco products is the crux of the substantial equivalence determination, changing the predicate product changes the fundamental basis of the analysis. An applicant that determines that a predicate change is necessary should withdraw the initial SE Report and resubmit the SE Report with the information related to the new predicate tobacco product as described in proposed § 1107.18.

In addition, under proposed § 1107.20(c), an applicant may not amend a closed SE Report, *e.g.*, one that FDA has refused to accept, closed, canceled, or issued an order for under proposed § 1107.44, or one that has been withdrawn under proposed § 1107.22. Proposed § 1107.20(d) also explains that FDA would review the additional information in the next review cycle (proposed § 1107.42 discusses review cycles). As explained in proposed § 1107.62, SE Reports, including amendments, would be submitted to CTP's Document Control Center. Phone calls and emails to FDA staff would not be considered amendments to an SE Report.

#### 5. Withdrawal by Applicant (Proposed § 1107.22)

Proposed § 1107.22 would permit an applicant to make a request to withdraw an SE Report unless FDA has closed the SE Report through an action in proposed § 1107.44 (all FDA actions in proposed § 1107.44 would close the SE

Report except for a request for additional information in proposed § 1107.44(b)). FDA has determined that withdrawal of an SE Report would benefit both the Agency and the applicant by potentially saving time and resources if the original SE Report might otherwise be insufficient or marketing authorization is no longer desired. The withdrawal request would state: (1) If the withdrawal is due to a health or safety concern related to the tobacco product; (2) the STN; and (3) the name of the new tobacco product that is the subject of the SE Report. This information would assist FDA in correctly identifying the SE Report to be withdrawn and also help inform FDA as to whether there were any concerns under section 909 of the FD&C Act (*e.g.*, relating to serious unexpected adverse experiences). Under proposed § 1107.22(b), an SE Report would be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn (see also proposed § 1107.40(e)).

The SE Report is an Agency record even if withdrawn. Thus, under proposed § 1107.22(c), FDA would retain the withdrawn SE Report consistent with Agency record retention schedules and policies and, under the Agency's public information regulations in part 20, would provide a copy to the applicant upon request subject to § 20.45. If the withdrawal request is made at the final review stage and FDA has identified unresolved deficiencies in the SE Report, FDA may provide a list of deficiencies in the communication that the Agency sends to the applicant acknowledging withdrawal. Under proposed § 1107.40(e), an SE Report would be considered withdrawn when FDA issues a notice stating that it is withdrawn.

#### 6. Change in Ownership of an SE Report (Proposed § 1107.24)

Proposed § 1107.24 would reflect that transfers in ownership of SE Reports occur. This proposed section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of an SE Report. Proposed § 1107.24 applies to both pending SE Reports and SE Reports that are the subject of an SE order. Under proposed § 1107.24, at the time of the transfer, the new and former applicants (or owners) of the SE Report would be required to submit certain information to the Agency. First, the former applicant would be required to submit a notice to FDA identifying the new applicant and stating that all of the former applicant's rights and responsibilities relating to the

SE Report have been transferred to the new applicant. Second, the new applicant would be required to submit a signed notice to FDA containing the following information:

- To the extent applicable, the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report (*e.g.*, this could be an agreement by the new applicant to conduct studies the former applicant had agreed to conduct in support of a request for an extension of time to respond to a deficiency);
- The date that the change in ownership is effective;
- Either a statement that the new applicant has a complete copy of the SE Report that FDA determined was substantially equivalent (including any amendments, or any records required to be kept under proposed § 1107.58); or a statement of intent to request a copy of the SE Report under the Freedom of Information Act (FDA's implementing regulations are in part 20); and
- A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

Although FDA expects that the new applicant would have a copy of the SE Report from the former applicant, if the new applicant requests a copy of the SE Report from FDA, FDA would provide a copy to the new applicant, subject to the Freedom of Information Act requirements as implemented by FDA at part 20 and under the fee schedule in § 20.45.

The new applicant also would be required to make available all required records upon inspection by FDA (proposed § 1107.58 would impose a recordkeeping requirement). The information required to be made available for inspection would include raw data and other information necessary to substantiate the SE Report.

#### C. FDA Review (Proposed Subpart D)

##### 1. Communications Between FDA and Applicants (Proposed § 1107.40)

Proposed § 1107.40 would establish general principles and provide clarity regarding communications between FDA and applicants during review of an SE Report. Proposed § 1107.40(a) explains that, during the course of FDA's review of an SE Report, FDA may seek to communicate with applicants about relevant matters, including scientific and procedural issues that arise during the review process. Communications regarding medical issues may arise if adverse events reports exist for the tobacco product.

FDA may use a variety of methods to communicate with applicants, such as telephone conversations, letters, or emails, depending on the circumstances and issues. FDA would document any communications regarding an SE Report in accordance with 21 CFR 10.65.

Proposed § 1107.40(b) would provide that applicants and representatives of the Agency may have meetings to discuss scientific and other issues. Applicants interested in requesting meetings would direct their requests to the Office of Science through the Document Control Center. For further information, applicants may review the guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (May 25, 2012, 77 FR 31368; revised guidance issued July 2016). As discussed in this guidance, FDA does not intend to grant meetings in most circumstances to discuss an applicant's questions related to a pending SE Report because the timing is frequently inappropriate (*e.g.*, premature or late, depending on stage of review) and such meetings are generally an inefficient or duplicative use of resources. For example, the applicant may be seeking substantive information while FDA's review is underway but before FDA has issued a deficiency letter or other response. Please note that each SE Report has a specific CTP contact to whom an applicant may ask clarifying questions, which helps ensure faster and more direct responses. FDA specifically requests public comment on the proposed decision to not grant meetings to discuss an applicant's questions related to a pending SE Report. Specifically, FDA seeks to understand if there are reasons why such meetings may be necessary for an applicant to respond to a deficiency letter or if the absence of such meetings present obstacles to the applicant in responding to deficiency letters.

Proposed § 1107.40(c) would provide that, upon receipt of an SE Report under proposed § 1107.18, FDA would either refuse to accept the SE Report or issue an acknowledgement letter. FDA requests comment on what a reasonable period of time would be within which such refusal to accept or acknowledgement of receipt letters should be issued.

Proposed § 1107.40(d) addresses FDA's notification of deficiencies in an SE Report submitted under proposed § 1107.18. FDA reviewers would make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and, if appropriate, the data needed to enable

the Agency's review. For example, a reviewer might inform the applicant that a signature is needed for a certification, that provided test results have last values cutoff or appear to have a typographical error, or that the SE Report is missing a reference for support. This communication is intended to give applicants an opportunity to correct deficiencies in the SE Report and to submit an amendment if needed.

Proposed § 1107.40(e) explains that an SE Report would be considered withdrawn when FDA issues a notice stating that it is withdrawn, which would ensure that FDA has received the withdrawal notification and that both FDA and the applicant now consider the SE Report as withdrawn.

FDA invites public comments on the following topics related to reasonable time periods to respond to a deficiency letter:

- Appropriate timelines for responding to a deficiency letter identifying missing information that is described in the final rule;
- Appropriate timelines for responding to a deficiency letter identifying missing information that requests additional information not described in the final rule;
- When requests for extensions of time to respond to a deficiency letter should be granted, and
- Whether or not deadlines to respond to deficiency letters should be tailored to the relative burden of the request.

## 2. Review Cycles (Proposed § 1107.42)

Proposed § 1107.42(a) would set forth the timeframe for FDA's initial review cycle. The "initial review cycle" would consist of the 90 calendar days following: (1) FDA's receipt of the SE Report and determination that a predicate product is grandfathered (for SE Reports that claim the predicate product was commercially marketed in the United States as of February 15, 2007, and FDA has not already determined the tobacco product is grandfathered) or (2) FDA's receipt of an SE Report (for SE Reports that contain a predicate product that was previously found substantially equivalent or for which FDA has previously determined that the predicate product is grandfathered). As described in more detail in proposed § 1107.44, FDA intends to review the SE Report and communicate with the applicant or take an action on an SE Report during this time period. At any time before FDA issues an order on the SE Report, the applicant would be allowed to withdraw it under proposed § 1107.22.

Proposed § 1107.42(b) would provide for the use of additional review cycles to complete FDA's review of an SE Report. If FDA issues a deficiency letter for an SE Report under proposed § 1107.40(d), FDA would stop reviewing the SE Report until it received a response to the notification of deficiencies (or deficiency letter) or the timeframe specified in the letter has elapsed. If the applicant fails to provide a response within the time period provided, FDA would issue an order denying marketing authorization for the new tobacco product under the criteria set forth in § 1107.48. If the applicant provides a response within the allotted timeframe, but FDA identifies the need for additional information as a result of this response, FDA could issue an additional deficiency notification. Each response would begin a new 90 calendar day review cycle for FDA to review the response.

FDA's intent is to complete review of an SE Report submitted under proposed § 1107.18 within a maximum of 270 review days (*i.e.*, three 90-day review cycles). Based on FDA's review experience, an SE Report should be resolved within three review cycles. If fewer review cycles are needed, FDA intends to decide in a shorter time period. Section 1107.40 would not obligate FDA to notify applicants of deficiencies in all circumstances before taking an action on an SE Report per proposed § 1107.44 or proposed § 1107.48. In any case where the SE Report has significant deficiencies, FDA might issue an order denying marketing authorization without providing additional opportunities to provide the missing information. Examples of significant deficiencies include when an SE Report provides no scientific evidence to substantiate a statement from the applicant that the new tobacco product does not raise different questions of public health or when an SE Report has multiple deficiencies but the applicant does not provide responses to all of the deficiencies. FDA requests public comment on whether FDA should provide specific timeframes within which applicants would need to respond to deficiency letters, along with an explanation as to why the proposed timeframes may be suitable for addressing the concerns commonly cited in the letters and why.

Proposed § 1107.42(c) states that, in the event that an applicant's response to FDA's deficiency notification(s) does not provide adequate information or the applicant provides information but the SE Report remains deficient, FDA intends to issue an order denying market authorization under the criteria

set forth in proposed § 1107.48. The applicant also could make a written request to withdraw the SE Report under proposed § 1107.22 at any time before FDA issues an order regarding the SE Report.

## 3. FDA Action on an SE Report (Proposed § 1107.44)

Proposed § 1107.44 lists six actions FDA may take after completing review of an SE Report:

- First, FDA could refuse to accept the SE Report and not begin substantive scientific review if the SE Report does not comply with the requirements of proposed § 1107.18 (this action would stop the review clock and end the review cycle). For example, FDA could refuse to accept an SE Report that was not written in English as required under § 1107.18(b), or did not provide the information on product composition as required under § 1107.19(c)(1). Or, FDA could advise the applicant that the SE Report is not appropriate under chapter IX of the FD&C Act because the product does not meet the definition of a tobacco product under section 201(rr) of the FD&C Act.

- Second, FDA could request additional information as provided in proposed § 1107.40(d).

- Third, FDA could issue a letter closing the SE Report if it not possible to make a determination on an SE Report (sometimes referred to as an administrative closure, for example, which we might do when there is no way to determine if a new product is SE or NSE and additional information is unavailable);

- Fourth, FDA could issue a letter canceling the SE Report if FDA finds it mistakenly acknowledged the SE Report, *e.g.*, the SE Report does not pertain to a new tobacco product;

- Fifth, FDA could issue an order finding the new tobacco product to be substantially equivalent and in compliance with the requirements of the FD&C Act under proposed § 1107.46.

- Sixth, FDA could issue an order denying marketing authorization under proposed § 1107.48 (NSE order) because:

- The applicant has failed to provide the information needed for FDA to find that the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed in the United States on February 15, 2007;

- The new tobacco product is not substantially equivalent to a tobacco product that was commercially marketed in the United States on February 15, 2007; or

○ The new tobacco product is not in compliance with the requirements of the FD&C Act. For example, a new tobacco product is not in compliance with the requirements of the FD&C Act if the manufacturer of such product is in arrears with respect to its user fees; therefore, FDA would issue an NSE order.

#### 4. Issuance of an Order Finding a New Tobacco Product Substantially Equivalent (Proposed § 1107.46)

Proposed § 1107.46 would explain that if, after review, FDA determines that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007, and in compliance with the FD&C Act, the Agency would send the applicant an order authorizing the marketing of the product. The marketing authorization would be effective on the date the order is issued, which would typically be noted on the first page of the order.

#### 5. Issuance of an Order Denying Marketing Authorization (Proposed § 1107.48)

Proposed § 1107.48(a) would provide that, in general, if FDA: (1) Is unable to determine that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007, or (2) determines that the new tobacco product is not in compliance with the FD&C Act, the Agency would issue an NSE order indicating that the manufacturer cannot market the new tobacco product. FDA would communicate this decision to the applicant in writing. Proposed § 1107.48(b) provides that the NSE order would describe the basis for denying marketing authorization. FDA intends to describe any deficiencies that FDA has identified in an SE Report.

#### 6. Rescission of Order (Proposed § 1107.50)

Proposed § 1107.50 would provide the procedural mechanism for FDA to rescind an SE order and describes the grounds for when an SE order may be rescinded. FDA intends to exercise this authority in a judicious and timely way in specific circumstances. FDA is proposing this provision based on our authority to issue an order only when it can make the findings provided in section 910(a)(2)(A)(i) of the FD&C Act and our authority to promulgate regulations for the efficient enforcement of the FD&C Act (section 701 of the FD&C Act). FDA's inherent authority to timely revisit and reconsider prior

decisions is also supported by case law, with the inherent authority for timely administrative reconsideration premised on the notion that the "power to reconsider is inherent in the power to decide." See *Ivy Sports Med. LLC, v. Burwell*, 767 F.3d 81, 86 (D.C. Cir. 2014) (quoting *Albertson v. FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950)). Where, as here, nothing in the Tobacco Control Act suggests that Congress intended to displace this inherent authority in the context of SE determinations, FDA may rescind an SE order based on its inherent authority. If, after issuing an SE order, FDA later determines, for example, that the order was based on false information or there was an error in information upon which the SE order is based, FDA would rescind the SE order. This proposed section would provide that—

- First, FDA may rescind an SE order if, after an order has issued, FDA becomes aware that the tobacco product for which the order has been issued:

- Does not have the same characteristics as the predicate tobacco product or
- has different characteristics and there is insufficient information demonstrating that it was not appropriate to require a premarket tobacco product application under section 910(b) of the FD&C Act because the product does not raise different questions of public health.

- Second, FDA may rescind an SE order if, after an order has issued, FDA becomes aware that the SE Report (including any submitted amendments) contains an untrue statement of material fact.

- Third, FDA may rescind an SE order if the SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent, and the predicate tobacco product relied on in the SE Report has been found ineligible because its SE Report (including any submitted amendments) contains an untrue statement of material fact, and/or a predicate product on which any of the previous substantial equivalence determinations was based, going back to the original grandfathered product, has been found ineligible because its SE Report (including any amendments) contained an untrue statement of material fact.

- Fourth, FDA may rescind an SE order if FDA or the applicant has removed from the market due to a health or safety concern related to the tobacco product:

- The predicate product on which the substantial equivalence determination is based and/or

- a predicate product on which any of the previous substantial equivalence determinations is based, going back to the original grandfathered product, if the SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent. FDA may rescind in this scenario because the new tobacco product is SE to, or is in the same generational line as a predicate tobacco product with safety issues, and, therefore, may present similar safety concerns.

Proposed § 1107.50(b) states that, generally, FDA would rescind an SE order only after it has provided notice to the applicant and an opportunity for a hearing under part 16. FDA is proposing to amend § 16.1 to add a reference § 1107.50. FDA encourages applicants to bring errors to the Agency's attention that may necessitate rescission, and FDA intends to work with applicants in such scenarios.

In addition, FDA may need to rescind an order without providing notice and a prior opportunity for a hearing if FDA finds that the continued marketing of the tobacco product presents a serious risk to public health, *e.g.*, if the applicant represented that the new tobacco product conformed to a tobacco product standard, but FDA later determined that the new tobacco product did not conform to a tobacco product standard in a way that presents a serious risk to public health. Another example would be if FDA identifies data integrity issues during an inspection that would lead FDA to believe that the tobacco product presents a serious risk to public health. In these cases, FDA would provide the applicant an opportunity for a hearing as soon as possible after the rescission.

#### D. Miscellaneous (Proposed Subpart E)

Subpart E describes other procedures and requirements related to SE Reports, including record retention, electronic submission requirements, foreign data, and confidentiality considerations.

##### 1. Record Retention (Proposed § 1107.58)

Consistent with the authority to require recordkeeping under section 909 of the FD&C Act, proposed § 1107.58, would require applicants receiving an order under proposed § 1107.46 authorizing the marketing of a new tobacco product to maintain all records supporting that SE Report for at least 4 years from the date of the order even if such product is discontinued. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA

inspection under section 704 and 905(g) of the FD&C Act. The records would be required to be legible, written in English or an English translation provided, and available for inspection and copying by officers or employees designated by the Secretary of Health and Human Services. Applicants that have stopped marketing a tobacco product may want to retain the records for a longer period, if the product might be reintroduced in order to avoid the time and expense of having to generate the information again.

## 2. Confidentiality (Proposed § 1107.60)

Proposed § 1107.60(a) states that FDA would determine the public availability of any part of any SE Report and other content related to an SE Report as provided under this proposed section and part 20 (Public Information). The Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as certain provisions of the FD&C Act, *e.g.*, section 301(j) (21 U.S.C. 331(j)) and section 906(c) (21 U.S.C. 387f(c)), govern the disclosure of the existence of a pending SE Report and the information contained in such an SE Report. Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure. One such provision, 5 U.S.C. 552(b)(4), exempts records that are “trade secrets and commercial or financial information obtained from a person and privileged or confidential” from the requirement of mandatory disclosure. Part 20 of FDA’s regulations sets forth FDA’s general regulations concerning public availability of FDA records.

Like with drugs and devices, the intent to market a tobacco product is often considered confidential commercial information, as premature disclosure could result in a competitive advantage to competitors. Therefore, FDA is proposing § 1107.60(b)(1), which would address the confidentiality of an SE Report prior to the issuance of an order under either proposed § 1107.46 or proposed § 1107.48. Under the proposed regulation and consistent with part 20, FDA would not publicly disclose the existence of an SE Report unless the applicant has publicly disclosed or acknowledged the existence (as such disclosure is defined in § 20.81), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted the SE Report to FDA.

Proposed § 1107.60(b)(2) provides that FDA would not disclose the existence or contents of an FDA communication with an applicant regarding its SE Report except to the extent that the

applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of or contents of that particular FDA communication. Proposed § 1107.60(b)(3) provides that FDA would not disclose information contained in an SE Report unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information contained in an SE Report, FDA may disclose that particular information.

Proposed § 1107.60(c) would address the disclosure of data and information after an order is issued under proposed § 1107.46. This proposed section would provide that, after an order under § 1107.46 (finding a new tobacco product substantially equivalent), FDA would make the following information related to the SE Report and order available for public disclosure upon request or at FDA’s own initiative, including information from amendments to the SE Report and FDA’s reviews of the SE Report: (1) All data previously disclosed to the public, as such disclosure is defined in § 20.81; (2) any protocol for a test or study, except to the extent it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61; (3) information and data submitted to demonstrate that the new tobacco product does not raise different questions of public health, except to the extent it is shown to fall within the exemptions established in § 20.61 for trade secrets and confidential commercial information, or in § 20.63 for personal privacy; (4) correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, except to the extent it is shown to fall within the exemptions in § 20.61 for trade secrets and confidential commercial information, or in § 20.63 for personal privacy; and (5) the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to submit an environmental assessment under part 25 of this chapter.

Even after issuance of an order under § 1107.48 (Denying marketing authorization), the applicant’s intent to

market may still constitute confidential commercial information, as the applicant may still be planning to market the new tobacco product that is the subject of the SE Report (*e.g.*, by submitting a new SE Report, a PMTA, or a request for exemption from substantial equivalence, or by seeking further review of the denial). Therefore, proposed § 1107.60(d) addresses the disclosure of data and information after FDA issues an order under § 1107.48 (Denying marketing authorization). Under this proposed subsection, FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA’s own initiative except to the extent the information is otherwise exempt from disclosure under part 20. Information FDA may disclose includes the tobacco product category (*e.g.*, cigarette), tobacco product subcategory (*e.g.*, filtered), package size, and the basis for the order denying marketing authorization.

Proposed § 1107.60(e) addresses disclosure of the health information summary or statement and would provide that health information required by section 910(a)(4) of the FD&C Act, if submitted as part of the SE Report (which includes any amendments), would be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA would make publicly available on FDA’s website the responsible official to whom a request for health information may be made. FDA intends to include this information on our website to ensure that the information is easily accessible to requestors.

## 3. Electronic Submission (Proposed § 1107.62)

Based on our authority in section 905 of the FD&C Act to prescribe the format of SE Reports, proposed § 1107.62(a) and (b) would require the applicant to submit the SE Report and supporting and other related documents in an electronic format that FDA can process, read, review, and archive unless a waiver from this requirement is requested by the applicant and FDA grants the waiver. Reasons that an applicant might request a waiver would include that the applicant has no access to email or a computer. Under proposed § 1107.62(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver. FDA is proposing § 1107.62 based on FDA’s general experiences with electronic submission, which FDA

has found helps facilitate premarket reviews because electronic submission typically has enabled FDA to receive, open, and read a submission more quickly than a submission submitted on paper through postal mail. If this rule is finalized, FDA intends to provide information on submitting information in an electronic format that FDA can process, read, review and archive (e.g., method of transmission, media, file formats, preparation, organization of files, accompanying metadata) (<https://www.fda.gov/TobaccoProducts/default.htm>). FDA intends to update this information as needed (e.g., to accommodate changes in technology).

**IV. Other Issues for Consideration**

In addition to comments and information on the proposed requirements described in section III, FDA is also seeking comments and information on whether some modifications to tobacco products that result in a new tobacco product, beyond those eligible for an exemption from substantial equivalence, might be handled through a “categorical” approach to substantial equivalence. Under such an approach, FDA would establish categories of modifications, and if a modification is within a category, the applicant could then submit a streamlined SE Report that identifies the modification and demonstrates substantial equivalence. FDA is soliciting concerns or benefits of this type of approach, along with information on the types of modifications or categories that might be handled in this way, or should not be handled this way.

**V. Paperwork Reduction Act of 1995**

This proposed rule contains information collection provisions that 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). A description of these provisions is given in the

*Description* section of this document with an estimate of the annual reporting and recordkeeping. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each 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.

*Title:* Substantial Equivalence Reports for Tobacco Products.

*Description:* Tobacco Products, Substantial Equivalence Reports, Requirements for Submitting Information Needed to Determine Substantial Equivalence and Maintaining Records to Support a Substantial Equivalence Report.

This proposed rule would establish requirements for the content and format of substantial equivalence (SE) Reports (proposed §§ 1107.18 and 1107.19). Most of the proposed requirements would mirror current practices and recommendations related to the submission of SE Reports, including information related to part 25 (environmental considerations), but the rule would provide both applicants and FDA more certainty regarding the content and format the SE Reports. A health information summary or statement would continue to be required

(section 910(a)(4) of the FD&C Act) and the health summary or response to a request would be required to be in the format of a redacted SE Report, along with any additional health information about the new tobacco product, including any information, research, or data about adverse health effects, that the applicant has or knows about and that is not contained in the SE Report.

As is currently the practice, the proposed rule would continue to permit amendments for SE Reports submitted under proposed § 1107.18, e.g., to address deficiencies (proposed § 1107.20). Also in accordance with current practice, the proposed rule would continue to permit withdrawals (proposed § 1107.22) of pending SE Reports. The proposed rule would also propose requirements for when the ownership of an SE Report changes to ensure that FDA has information related to the current applicant (proposed § 1107.24).

The proposed rule would establish a recordkeeping requirement, under which applicants would be required to maintain records supporting the SE Report for an authorized new tobacco product for 4 years from the date of an order finding substantial equivalence, even if such product is discontinued (proposed § 1107.58).

The proposed rule would require that respondents submit an SE Report in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA (proposed § 1107.62). FDA created two new forms for submission; Form FDA 3964, Tobacco Amendment and General Correspondence; and Form FDA 3965, Tobacco Substantial Equivalence Report Submission.

*Description of Respondents:* Manufacturers of tobacco products who submit SE Reports.

*Existing Burden OMB Control Number* 0910–0673

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a) .....	410	1	410	300	123,000
Full SE 905(j)(1)(A)(i) and 910(a) Bundled .....	250	1	250	90	22,500
Product Quantity Change SE Report .....	264	1	264	87	22,968
Product Quantity Change Bundled SE Report .....	55	1	55	62	3,410
Totals .....					171,878

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> This chart represents the currently OMB approved burden for the SE program.

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a) .....	683	1	683	300	204,900
Full SE 905(j)(1)(A)(i) and 910(a) Bundled .....	456	1	456	90	41,040
Product Quantity Change SE Report .....	239	1	239	87	20,793
Product Quantity Change Bundled SE Report .....	192	1	192	62	11,904
Total .....					278,637

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Draft burden not yet OMB approved.

In the **Federal Register** of September 6, 2018 (83 FR 45251), FDA published a notice soliciting comments on the extension of the current SE program. The numbers above in table 10 represent the tentative revisions which have not yet been approved by OMB. These

estimates revise the number of reports under OMB control number 0910–0673 and take into account updated registration and listing data. The previous estimate for reports was 979 and total burden hours were 171,878. This chart accounts for the tentative

increase in burden due to the expected rise in submissions other than any increases in burden due to the proposed rule, if finalized.

*New Reporting Per Rule*

TABLE 11—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3965 Tobacco Substantial Equivalence Report Submission .....	1,570	1	1,570	.5	785
FDA 3964 Tobacco Amendment and General Correspondence .....	628	1	628	.083	52
Waiver from Electronic submission 1107.62(b) .....	240	1	240	.25	60
Totals .....					897

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Draft burden not yet OMB approved.

*Final Combined Reporting Burden*  
(Tables 10 +11)

TABLE 12—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SE Report 1107.18 .....	683	1	683	300	204,900
Bundled SE 1107.18 .....	456	1	456	90	41,040
SE Report where applicant provides certification for identical characteristics 1107.18(g) and 1107.18(1)(2) .....	239	1	239	87	20,793
SE Report where applicant provides certification for some identical characteristics (bundled) 1107.18(g) and 1107.18(1)(2) .....	192	1	192	62	11,904
FDA 3965 Tobacco Substantial Equivalence Report Submission .....	1,570	1	1,570	.5	785
FDA 3964 Tobacco Amendment and General Correspondence Report .....	628	1	628	.083	52
Waiver from Electronic submission 1107.62(b) .....	240	1	240	.25	60
Totals .....					279,534

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Draft burden not yet OMB approved.

*New Final Recordkeeping Burden*

TABLE 13—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1 2</sup>

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping SE Report under 1107.18 1107.58 ....	471	1	471	2.5	1,178

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Draft burden not yet OMB approved.

FDA's estimates are based on experience with SE Reports, registration and listing data, interactions with the industry, and information related to other regulated products. As explained above, taking into account the updated registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570. That estimate is not expected to change as a result of the proposed rule, if finalized.

When groups of full SE Reports or SE Reports that each contain a certification that some characteristics are identical have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the substantial equivalence pathway to market their products. Table 9 describes the annual reporting burden for compliance with the requirements to demonstrate substantial equivalence under the FD&C Act. We do not expect a large burden increase for this program, as, without the proposed rule, manufacturers would routinely submit SE Reports for new tobacco products, and the Agency believes most respondents are currently practicing most of the proposed requirements. FDA will revise this collection with the new burden. FDA requests public comments on the estimated burden associated with the requirements associated with this rule and whether there is any evidence, information, or data to support alternate burden estimates.

Table 11 describes the annual reporting burden as a result of the requirements proposed in §§ 1107.18 and 1107.19, implementing the substantial equivalence requirements of section 905(j)(1)(A)(i) and 910(a) of the FD&C Act. This proposed rule would require manufacturers to submit SE Reports electronically (proposed § 1107.62). We estimate that it would initially take about 30 minutes per

product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3964 will take 5 minutes as applicants can copy and paste from the first submission. Proposed 1107.62(b) also allows for waivers from the electronic format requirement. FDA estimates that 240 respondents or 15 percent of SE Reports (1,570) will submit a waiver.

Based on updated information, FDA estimates that it will receive 683 full initial SE Reports for a new tobacco product each year under proposed § 1107.18 that take a manufacturer approximately 300 hours to prepare. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report. We expect to receive 456 bundled SE Reports under proposed § 1107.18 (other than the initial SE Report in the bundle) at approximately 90 hours per response for a total of 41,040 hours.

In the absence of more specific information concerning SE Reports where applicants provide a certification for some identical characteristics under proposed § 1107.18(g) and 1107.18(l)(2), FDA estimates receiving 239 such SE Reports at 87 hours per response for a total of 20,973 hours. We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under proposed §§ 1107.18(g) and 1107.18(l)(2) (other than the initial SE Report in the bundle) at 62 hours per response for a total of 11,904 hours. Although we believe that the number of SE Reports that include a certification will increase because the proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product, in the absence of specific information on how many more applicants might choose to

certify, we are maintaining our previous estimates at this time. We request comment on these estimates.

FDA has based these estimates on the full analysis of economic impacts and experience with the recently-revised existing information collection that applies to tobacco products. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under proposed § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report.

Based on FDA's experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours preparing an environmental assessment for a full SE Report under proposed § 1107.18.

Generally, an applicant may withdraw its SE Report after submission (proposed § 1107.22), change the ownership of its SE Report (proposed § 1107.24), and amend its SE Report (proposed § 1107.20). The information required to grant these requests is already being collected, so we do not expect a change in burden.

FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 2.5 hours per record for a total of 1,178 recordkeeping hours.

FDA estimates that the burden for new requirements will increase this collection by 108,834 (107,656 + 1,178 recordkeeping). The burden for the submission of substantial equivalence information is estimated to total 280,712 hours (279,534 reporting and 1,178 recordkeeping). This proposed rule also refers to previously approved collections of information found in FDA regulations. Proposed § 1107.40 references meetings that may be held with applicants who want to meet with FDA to discuss scientific and other issues. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance entitled "Meetings with Industry and Investigators on the Research and Development of Tobacco Products." The collections of information in the guidance referenced have been approved under OMB control number

0910-0731. In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i), certain new tobacco products may use the exemption premarket pathway, see 21 CFR 1107.1. The collections of information found in 21 CFR 1107.1 have been approved under OMB control number 0910-0684.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

#### **VI. Executive Order 13132: Federalism**

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to “construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”

Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) is an express preemption provision. Section 916(a)(2) provides that “no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . premarket review.” Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

#### **VII. Consultation and Coordination With Indian Tribal Governments**

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal

Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

#### **VIII. Analysis of Environmental Impact**

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist to indicate that the specific proposed action may significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### **IX. Economic Analysis of Impacts**

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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). We believe that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have determined that the compliance costs are less than 0.1 percent of revenues, we propose to certify that the rule would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$150 million, using the most current (2017) Implicit

Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed rule would impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from \$0.60 million to \$2.64 million, with a primary estimate of \$1.61 million at a 3 percent discount rate, and from \$0.56 million to \$2.32 million, with a primary estimate of \$1.43 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from \$0.07 million to \$0.31 million, with a primary estimate of \$0.19 million at a 3 percent discount rate and from \$0.08 million to \$0.33 million, with a primary estimate of \$0.20 million at a 7 percent discount rate.

The benefits of this proposed rule are potential time-savings to industry and cost-savings to government. This proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. In this proposed rule, we intend to shorten review times for SE Reports. In addition, based on our experience with prior SE Reports, we believe this proposed rule would lead to better SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which would result in cost-savings. We estimate that the present value of government cost-savings ranges from \$15 million to \$198 million at a 3 percent discount rate, and from \$12 million to \$163 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from \$1.7 million to \$23.2 million at both 3 and 7 percent discount rates.

The qualitative benefits of this proposed rule include additional clarity to industry about the requirements for the content and format of SE Reports. The proposed rule would also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this proposed rule would make the SE pathway more predictable.

The proposed rule’s costs and benefits are summarized in Table 14 entitled “Economic Data: Costs and Benefits Statement.”

TABLE 14—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Low estimate	Primary estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
<b>Benefits:</b>							
Annualized Monetized \$millions/year.	1.7	7.2	23.2	2016	7	10	Cost-savings to government. Cost-savings to government.  Greater certainty for SE applicants.
Annualized Quantified	1.7	7.2	23.2	2016	3	10	
Annualized Qualitative				2016	7	10	
Quantified				2016	3	10	
Qualitative							
<b>Costs:</b>							
Annualized Monetized \$millions/year.	0.08	0.20	0.33	2016	7	10	
Annualized Quantified	0.07	0.19	0.31	2016	3	10	
Annualized Qualitative				2016	7	10	
Quantified				2016	3	10	
Qualitative							
<b>Transfers:</b>							
Federal Annualized Monetized \$millions/year.				2016	7	10	
				2016	3	10	
From:				To:			
Other Annualized Monetized \$millions/year.				2016	7	10	
				2016	3	10	
From:				To:			

Effects:  
 State, Local or Tribal Government: No effect  
 Small Business: No effect  
 Wages: No effect  
 Growth: No effect

In line with Executive Order 13771, in Table 15 we estimate present and annualized values of costs and cost-savings over an infinite time horizon. Our primary estimate of the present value over an infinite time horizon of net costs due to this proposed rule is

– \$101.4 million at a 7 percent discount rate, and – \$237.7 million at a 3 percent discount rate. Our primary estimate of the annualized net costs is – \$7.1 million at a 7 percent discount rate and – \$7.1 million at a 3 percent discount rate. Table 15 summarizes the costs,

cost-savings and net costs of this proposed rule. Based on these cost-savings this proposed rule, if finalized, would be considered a deregulatory action under E.O. 13771.

TABLE 15—E.O. 13771 SUMMARY TABLE  
 [In \$ Millions 2016 dollars, over infinite time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	\$2.05	\$0.57	\$3.56	\$3.75	\$0.69	\$6.92
Present Value of Cost Savings	103.49	24.84	331.18	241.48	57.96	772.75
Present Value of Net Costs	(101.4)	(24.3)	(327.6)	(237.7)	(57.3)	(765.8)
Annualized Costs	0.14	0.04	0.25	0.11	0.02	0.21
Annualized Cost Savings	7.24	1.74	23.18	7.24	1.74	23.18
Annualized Net Costs	(7.1)	(1.7)	(22.9)	(7.1)	(1.7)	(23.0)

Note: Values in parentheses denote net negative costs (i.e., cost-savings).

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 54) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

**X. References**

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this

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## XI. Effective Date

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

## List of Subjects

### 21 CFR Part 16

Administrative practice and procedure.

### 21 CFR Part 1107

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended as follows:

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

- 1. The authority citation for part 16 continues to read as follows:

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

- 2. In § 16.1(b)(2) add in numerical sequence an entry for "§ 1107.50" to read as follows:

### § 16.1 Scope.

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

§ 1107.50, relating to rescission of an order finding a tobacco product substantially equivalent.

\* \* \* \* \*

## PART 1107—EXEMPTIONS AND SUBSTANTIAL EQUIVALENCE REPORTS

- 3. The authority citation for part 1107 is revised to read as follows:

**Authority:** 21 U.S.C. 371, 374, 387b, 387c, 387e(j), 387i, and 387j.

- 4. The heading of part 1107 is revised to read as set forth above.

- 5. Add subparts B through E to read as follows:

### Subpart B—General

Sec.

1107.10 Scope.

1107.12 Definitions.

### Subpart C—Substantial Equivalence Reports

1107.16 Submission of a substantial equivalence report.

1107.18 Required content and format of a report.

1107.19 Comparison information.

1107.20 Amendments.

1107.22 Withdrawal by applicant.

1107.24 Change in ownership of an SE report.

### Subpart D—FDA Review

1107.40 Communications between FDA and applicants.

1107.42 Review cycles.

1107.44 FDA action on an SE report.

1107.46 Issuance of an order finding a new tobacco product substantially equivalent.

1107.48 Issuance of an order denying marketing authorization.

1107.50 Rescission of order.

### Subpart E—Miscellaneous

1107.58 Record retention.

1107.60 Confidentiality.

1107.62 Electronic submission.

## Subpart B—General

### § 1107.10 Scope.

(a) Subparts B through E of this part apply to a substantial equivalence report (or SE Report) for a new tobacco product that has:

(1) Characteristics different from a predicate tobacco product and for which information is submitted to demonstrate it is not appropriate to regulate the product under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health; or

(2) The same characteristics as a predicate tobacco product.

(b) These subparts set forth procedures and requirements for the submission to FDA of an SE Report under sections 905 and 910 of the Federal, Food, Drug, and Cosmetic Act; the basic criteria for establishing substantial equivalence; and the general procedures FDA will follow when evaluating submissions.

### § 1107.12 Definitions.

For purposes of this part:

**Accessory** means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product; but

(i) Solely controls moisture and/or temperature of a stored product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

**Additive** means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating,

packaging, transporting, or holding), except that the term does not include tobacco or a pesticide chemical residue in or on raw tobacco, or a pesticide chemical.

*Applicant* means any manufacturer of tobacco products who is subject to chapter IX of the Federal Food, Drug, and Cosmetic Act that submits a premarket application to receive marketing authorization for a new tobacco product.

*Brand* means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

*Characteristic* means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

*Commercial distribution* means any distribution of a tobacco product to consumers or to another person through sale or otherwise, but does not include interplant transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. "Commercial distribution" does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term "commercial distribution" has the same meaning, except that it does not include distribution of a tobacco product that is neither imported nor offered for import into the United States.

*Component or part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product.

Component or part excludes anything that is an accessory of a tobacco product.

*Composition* means the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product.

*Constituent* means any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an

emission from a tobacco product, or any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the tobacco product to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

*Container closure system* means any packaging materials that are a component or part of a tobacco product.

*Design* means the form and structure concerning, and the manner in which, components or parts, ingredients, software, and materials are integrated to produce a tobacco product.

*Distributor* means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

*Finished tobacco product* means a tobacco product, including all components and parts, sealed in final packaging (e.g., filters or filter tubes sold separately to consumers or as part of kits).

*Grandfathered tobacco product* means a tobacco product that was commercially marketed in the United States as of February 15, 2007, and does not include a tobacco product exclusively in test markets as of that date. A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

*Harmful or potentially harmful constituent (HPHC)* means any chemical or chemical compound in a tobacco product or tobacco smoke or emission that:

(1) Is or potentially is inhaled, ingested, or absorbed into the body; and

(2) Causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

*Health information statement* means a statement, made under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, that the health information related to a new tobacco product will be made available upon request by any person.

*Health information summary* means a summary, submitted under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, of any health information related to a new tobacco product.

*Heating source* means the source of energy used to burn or heat a tobacco product.

*Ingredient* means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper,

filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

*Material* means an assembly of ingredients. Materials are assembled to form a tobacco product or components or parts of tobacco products.

*New tobacco product* means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

*Other features* means any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Such other features include harmful and potentially harmful constituents and any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product and are necessary for review.

*Package or packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

*Predicate tobacco product* means a tobacco product that is a grandfathered tobacco product or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

*Submission tracking number or STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and requests for grandfather determinations.

*Substantial equivalence or substantially equivalent* means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:

(1) Has the same characteristics as the predicate tobacco product; or

(2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate

to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

*Substantial equivalence report* or *SE Report* means a submission under section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act that includes the basis for the applicant's determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial substantial equivalence report and all subsequent amendments.

*Tobacco product* means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the Federal Food, Drug, and Cosmetic Act is a drug (section 201(g)(1)), a device (section 201(h)), or a combination product (section 503(g)).

*Tobacco product manufacturer* means any person, including a repacker or relabeler, who:

- (1) Manufactures, fabricates, assembles, processes, or labels a tobacco product, or
- (2) Imports a finished tobacco product for sale or distribution in the United States.

**Subpart C—Substantial Equivalence Reports**

**§ 1107.16 Submission of a substantial equivalence report.**

An applicant may submit a SE Report intended to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. The applicant must submit the SE Report at least 90 calendar days prior to the date the applicant intends to introduce or deliver for introduction a new tobacco product into interstate commerce for commercial distribution. The applicant cannot begin commercial distribution of the new tobacco product until FDA has provided the applicant an order stating that the Agency has determined that the new tobacco product is substantially equivalent to a predicate tobacco product, unless the

new tobacco product has received authorization to be marketed through another premarket pathway.

**§ 1107.18 Required content and format of a SE report.**

(a) *Overview.* The SE Report must provide information uniquely identifying the new tobacco product and the predicate tobacco product, and compare the new tobacco product to either a grandfathered tobacco product or a tobacco product that FDA previously found to be substantially equivalent. The SE Report must provide sufficient information as described in this section to enable FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed in the United States as of February 15, 2007. If FDA cites deficiencies and requests information to support a statement in the SE Report, the applicant must provide that information for review to continue, or FDA may issue an order under § 1107.48. FDA will refuse to accept an SE Report if it does not comply with this section. The SE Report must contain the following information:

- (1) General information (as described in paragraph (c) of this section);
- (2) Summary (as described in paragraph (d) of this section);
- (3) New tobacco product description (as described in paragraph (e) of this section);
- (4) Predicate tobacco product description (as described in paragraph (f) of this section), including a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the submission tracking number of the SE order finding the predicate product SE, or the submission tracking number of, or information to support, a grandfathered determination of the predicate tobacco product;
- (5) Comparison information (as described in paragraph (g) of this section);
- (6) Comparative testing information (as described in paragraph (h) of this section);
- (7) Statement of compliance with applicable tobacco product standards (as described in paragraph (i) of this section);

(8) Health information summary or statement that such information will be made available upon request (as described in paragraph (j) of this section);

(9) Compliance with 21 CFR part 25 (as described in paragraph (k) of this section); and

(10) Certification statement (as described in paragraph (l) of this section).

(b) *Format.* The applicant must submit the SE Report using the form(s) that FDA provides. The SE Report must contain a comprehensive index and table of contents, be well-organized and legible, and be written in English. As described in § 1107.62, the applicant must submit the SE Report and all information supporting the SE Report in an electronic format that FDA can process, read, review, and archive, unless FDA has provided a waiver.

(c) *General information.* The SE Report must include the following information, using the form FDA provides:

- (1) The date the SE Report is submitted;
- (2) Type of submission (e.g., the SE Report or amendment to a report);
- (3) FDA STN if previously assigned;
- (4) Any other relevant FDA STN, such as a request for grandfathered determination or SE Report previously found substantially equivalent (if applicable), and cross-references to meetings with FDA regarding the new tobacco product;
- (5) Applicant name, address, and contact information;
- (6) Authorized representative or U.S. agent (for a foreign applicant), including the name, address, and contact information;
- (7) For both the new and predicate tobacco products, the following information to uniquely identify the products:
  - (i) Manufacturer;
  - (ii) Product name, including the brand and sub brand (or other commercial name used in commercial distribution); and
  - (iii) Product category, product subcategory, and product properties (if the product does not have a listed product property, e.g., ventilation or characterizing flavor, the report must state "none" for that property) as provided in the following table:

Tobacco product category:	Tobacco product subcategory:	Product properties:
(A)Cigarettes .....	(1) Combusted, Filtered .....	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 millimeters (mm), 100 mm). —Diameter (e.g., 6 mm, 8.1 mm).

Tobacco product category:	Tobacco product subcategory:	Product properties:
(B) Roll-Your-Own Tobacco Products.	(2) Combusted, Non-filtered .....	<ul style="list-style-type: none"> <li>—Ventilation (<i>e.g.</i>, none, 10%, 25%).</li> <li>—Characterizing Flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> <li>—Package type (<i>e.g.</i>, hard pack, soft pack, clam shell).</li> <li>—Product quantity (<i>e.g.</i>, 20 cigarettes, 25 cigarettes).</li> <li>—Length (<i>e.g.</i>, 89 mm, 100 mm).</li> <li>—Diameter (<i>e.g.</i>, 6 mm, 8.1 mm).</li> <li>—Characterizing Flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(3) Combusted, Other .....	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, hard pack, soft pack, clam shell).</li> <li>—Product quantity (<i>e.g.</i>, 20 cigarettes, 25 cigarettes).</li> <li>—Length (<i>e.g.</i>, 89 mm, 100 mm).</li> <li>—Diameter (<i>e.g.</i>, 6 mm, 8.1 mm).</li> <li>—Ventilation (<i>e.g.</i>, none, 10%, 25%).</li> <li>—Characterizing Flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(4) Non-Combusted ( <i>e.g.</i> , a cigarette where the tobacco is heated not burned).	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, hard pack, soft pack, clam shell).</li> <li>—Product quantity (<i>e.g.</i>, 20 cigarettes, 25 cigarettes).</li> <li>—Length (<i>e.g.</i>, 89 mm, 100 mm).</li> <li>—Diameter (<i>e.g.</i>, 6 mm, 8.1 mm).</li> <li>—Ventilation (<i>e.g.</i>, none, 10%, 25%).</li> <li>—Characterizing Flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Source of energy (<i>e.g.</i>, charcoal, electrical heater).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(5) Cigarette, Co-Package .....	<p>For a new co-packaged tobacco product composed of multiple cigarette tobacco products, include, as applicable, all properties for each individual tobacco product, as identified in this section.</p>
	(1) Roll-Your-Own Tobacco Filler ..	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, bag, pouch).</li> <li>—Product quantity (<i>e.g.</i>, 20 g, 40 g).</li> <li>—Characterizing flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(2) Rolling Paper .....	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, bag, box, booklet).</li> <li>—Product quantity (<i>e.g.</i>, 50 sheets, 200 papers).</li> <li>—Length (<i>e.g.</i>, 79 mm, 100 mm, 110 mm).</li> <li>—Width (<i>e.g.</i>, 28 mm, 33 mm, 45 mm).</li> <li>—Characterizing flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(3) Filtered Cigarette Tube .....	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, bag, box).</li> <li>—Product quantity (<i>e.g.</i>, 100 tubes, 200 tubes).</li> <li>—Length (<i>e.g.</i>, 89 mm, 100 mm).</li> <li>—Diameter (<i>e.g.</i>, 6 mm, 8.1 mm).</li> <li>—Ventilation (<i>e.g.</i>, none, 10%, 25%).</li> <li>—Characterizing flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(4) Non-Filtered Cigarette Tube ....	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, bag, box).</li> <li>—Product quantity (<i>e.g.</i>, 100 tubes, 200 tubes).</li> <li>—Length (<i>e.g.</i>, 89 mm, 100 mm).</li> <li>—Diameter (<i>e.g.</i>, 6 mm, 8.1 mm).</li> <li>—Characterizing flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(5) Filter .....	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, bag, box).</li> <li>—Product quantity (<i>e.g.</i>, 100 filters, 200 filters).</li> <li>—Length (<i>e.g.</i>, 8 mm, 12 mm).</li> <li>—Diameter (<i>e.g.</i>, 6 mm, 8.1 mm).</li> <li>—Ventilation (<i>e.g.</i>, none, 10%, 25%).</li> <li>—Characterizing flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(6) Paper Tip .....	<ul style="list-style-type: none"> <li>—Package type (<i>e.g.</i>, bag, box).</li> <li>—Product quantity (<i>e.g.</i>, 200 tips, 275 tips).</li> <li>—Length (<i>e.g.</i>, 12 mm, 15 mm).</li> <li>—Width (<i>e.g.</i>, 27 mm).</li> <li>—Characterizing flavor(s) (<i>e.g.</i>, none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>

Tobacco product category:	Tobacco product subcategory:	Product properties:
(C) Smokeless Tobacco Products ..	(7) Roll-Your-Own Co-Package .....	—For a new co-packaged tobacco product composed of multiple RYO tobacco products, include, as applicable, all properties for each individual tobacco product (e.g., roll-your own tobacco, rolling paper, filtered cigarette tube, non-filtered cigarette tube, filter, paper tip) as identified in this section.
	(8) Other .....	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product.
	(1) Loose Moist Snuff .....	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20 grams (g), 2 ounces). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(2) Portioned Moist .....	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).
	(3) Snuff .....	—Product quantity (e.g., 22.5 g, 20 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 2 g/piece). —Portion length (e.g., 15 mm, 20 mm). —Portion width (e.g., 10 mm, 15 mm). —Portion thickness (e.g., 5 mm, 7 mm). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Loose Snuff .....	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20 g, 2 ounces). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Portioned Snuff .....	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 2 g/piece). —Portion length (e.g., 15 mm, 20 mm). —Portion width (e.g., 10 mm, 15 mm). —Portion thickness (e.g., 5 mm, 7 mm). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(6) Loose Dry Snuff .....	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20 g, 2 ounces). —Tobacco cut size (e.g., 0.05 mm, 0.07 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(7) Dissolvable .....	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20 g). —Portion count (e.g., 15 sticks, 20 tablets). —Portion mass (e.g., 1.5 g/strip, 1 g/piece). —Portion length (e.g., 10 mm, 15 mm). —Portion width (e.g., 5 mm, 8 mm). —Portion thickness (e.g., 3 mm, 4 mm). —Tobacco cut size (e.g., 0.05 mm, 0.07 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).	
(8) Loose Chewing Tobacco .....	—Package type (e.g., bag, pouch, wrapped). —Product quantity (e.g., 20 g, 3 ounces). —Tobacco cut size (e.g., 0.05 mm, 0.07 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).	

Tobacco product category:	Tobacco product subcategory:	Product properties:
(D) ENDS (Electronic Nicotine Delivery System).	(9) Portioned Chewing Tobacco ....	<ul style="list-style-type: none"> <li>—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).</li> <li>—Product quantity (e.g., 20 g).</li> <li>—Portion count (e.g., 10 bits).</li> <li>—Portion mass (e.g., 2 g/bit).</li> <li>—Portion length (e.g., 8 mm, 10 mm).</li> <li>—Portion width (e.g., 6 mm, 8 mm).</li> <li>—Portion thickness (e.g., 5 mm, 7 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(10) Smokeless Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple smokeless tobacco products, include, as applicable, all properties for each individual tobacco product as identified in this section.</li> </ul>
	(11) Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
	(1) Open E-Liquid .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bottle, box).</li> <li>—Product quantity (e.g., 1 bottle, 5 bottles).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—E-liquid volume (e.g., 10 milliliters (ml)).</li> <li>—Nicotine concentration (e.g., 0, 0.2 mg/ml).</li> <li>—PG/VG ratio (e.g., N/A, 0/100, 50/50).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(2) Closed E-Liquid .....	<ul style="list-style-type: none"> <li>—Package type (e.g., cartridge).</li> <li>—Product quantity (e.g., 1 cartridge, 5 cartridges).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—E-liquid volume (e.g., 10 ml).</li> <li>—Nicotine concentration (e.g., 0, 0.2 mg/ml).</li> <li>—PG/VG ratio (e.g., N/A, 0/100, 50/50).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(3) Closed E-Cigarette .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none, plastic clamshell).</li> <li>—Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—Length (e.g., 100 mm, 120 mm).</li> <li>—Diameter (e.g., 6 mm, 8 mm).</li> <li>—E-liquid volume (e.g., 2 ml, 5 ml).</li> <li>—Nicotine concentration (e.g., 0, 0.2 mg/ml).</li> <li>—PG/VG ratio (e.g., N/A, 0/100, 50/50).</li> <li>—Wattage (e.g., 100 W, 200 W).</li> <li>—Battery capacity (e.g., 100 mAh, 200 mAh).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
	(4) Open E-Cigarette .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none, plastic clamshell).</li> <li>—Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—Length (e.g., 100 mm, 120 mm).</li> <li>—Diameter (e.g., 8 mm, 14 mm).</li> <li>—E-liquid volume (e.g., 2 ml, 5 ml).</li> <li>—Wattage (e.g., 100 Watts (W), 200 W).</li> <li>—Battery capacity (e.g., 100 mAh, 200 mAh).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(5) ENDS Component .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none, plastic clamshell).</li> <li>—Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes).</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(6) ENDS Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple ENDS tobacco products, include, as applicable, all properties for each individual tobacco product as identified in this section.</li> </ul>
	(7) ENDS Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry).</li> </ul>

Tobacco product category:	Tobacco product subcategory:	Product properties:
(E) Cigars .....	(1) Filtered, Sheet-Wrapped Cigar	<ul style="list-style-type: none"> <li>—Additional properties needed to uniquely identify the tobacco product.</li> <li>—Package type (e.g., hard pack, soft pack, clam shell).</li> <li>—Product quantity (e.g., 20 filtered cigars, 25 filtered cigars).</li> <li>—Characterizing flavor (e.g., none, menthol).</li> <li>—Length (e.g., 89 mm, 100 mm).</li> <li>—Diameter (e.g., 6 mm, 8.1 mm).</li> <li>—Ventilation (e.g., none, 10%, 25%).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(2) Unfiltered, Sheet-Wrapped Cigar	<ul style="list-style-type: none"> <li>—Package type (e.g., box, film sleeve).</li> <li>—Product quantity (e.g., 1 cigar, 5 cigarillos).</li> <li>—Characterizing flavor (e.g., none, menthol).</li> <li>—Length (e.g., 100 mm, 140 mm).</li> <li>—Diameter (e.g., 8 mm, 10 mm).</li> <li>—Tip (e.g., none, wood tips, plastic tips).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(3) Leaf-Wrapped Cigar .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, film, sleeve, none).</li> <li>—Product quantity (e.g., 1 cigar, 5 cigars).</li> <li>—Characterizing flavor (e.g., none, whiskey).</li> <li>—Length (e.g., 150 mm, 200 mm).</li> <li>—Diameter (e.g., 8 mm, 10 mm).</li> <li>—Wrapper material (e.g., burley tobacco leaf, Connecticut shade grown tobacco leaf).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(4) Cigar Component .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, booklet).</li> <li>—Product quantity (e.g., 10 wrappers, 20 leaves).</li> <li>—Characterizing flavor (e.g., none, menthol, cherry).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(5) Cigar Tobacco Filler .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, pouch).</li> <li>—Product quantity (e.g., 20 g, 16 ounces).</li> <li>—Characterizing flavor (e.g., none, tobacco, menthol, cherry).</li> <li>—Tobacco cut size (e.g., 5 mm, 10 mm).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(6) Cigar Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple cigar tobacco products, include, as applicable, all properties for each individual tobacco product as identified previously.</li> </ul>
	(7) Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
(F) Pipe Tobacco Products .....	(1) Pipe .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none).</li> <li>—Product quantity (e.g., 1 pipe).</li> <li>—Length (e.g., 200 mm, 300 mm).</li> <li>—Diameter (e.g., 25 mm).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(2) Pipe Tobacco Filler .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, pouch).</li> <li>—Product quantity (e.g., 20 g, 16 ounces).</li> <li>—Characterizing flavor(s) (e.g., none, menthol, cavendish, cherry).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(3) Pipe Component .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bowl, shank, stem, screen, filter).</li> <li>—Product quantity (e.g., 1 bowl, 1 stem, 100 filters).</li> <li>—Characterizing flavor(s) (e.g., none, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product (if applicable).</li> </ul>
	(4) Pipe Co-Package .....	<ul style="list-style-type: none"> <li>—For a new co-packaged tobacco product composed of multiple pipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified previously.</li> </ul>
	(5) Other .....	<ul style="list-style-type: none"> <li>—Package type (e.g., bag, box).</li> <li>—Product quantity.</li> <li>—Characterizing flavor(s) (e.g., none, tobacco, menthol).</li> <li>—Additional properties needed to uniquely identify the tobacco product.</li> </ul>
(G) Waterpipe Tobacco Products ...	(1) Waterpipe .....	<ul style="list-style-type: none"> <li>—Package type (e.g., box, none).</li> <li>—Product quantity (e.g., 1 waterpipe).</li> <li>—Length (e.g., 200 mm, 500 mm).</li> </ul>

Tobacco product category:	Tobacco product subcategory:	Product properties:
	(2) Waterpipe Tobacco Filler .....	—Width (e.g., 100 mm, 300 mm). —Number of hoses (e.g., 1, 2, 4). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable). —Package type (e.g., bag, pouch). —Product quantity (e.g., 20 g, 16 ounces). —Characterizing flavor(s) (e.g., none, tobacco, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(3) Waterpipe Heat Source .....	—Package type (e.g., box, film sleeve, bag, none). —Product quantity (e.g., 150 g, 680 g). —Characterizing flavor(s) (e.g., none, menthol, apple). —Portion count (e.g., 20 fingers, 10 discs, 1 base). —Portion mass (e.g., 15 g/finger). —Portion length (e.g., 40 mm, 100 mm). —Portion width (e.g., 10 mm, 40 mm). —Portion thickness (e.g., 10 mm, 40 mm). —Source of energy (e.g., charcoal, battery, electrical). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(4) Waterpipe Component .....	—Package type (e.g., bag, box, none). —Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (e.g., none, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(5) Waterpipe Co-Package .....	—For a new co-packaged tobacco product composed of multiple waterpipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified in this section.
	(6) Waterpipe Other .....	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other .....	Other .....	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

(8) Address and the FDA Establishment Identifier (FEI) number(s) of the establishments involved in the manufacture and/or importation of the new and predicate tobacco products.

(d) *Summary.* The SE Report must include a summary at the beginning of the SE Report that includes the following:

(1) A concise description of the characteristics of the new tobacco product;

(2) A statement as to whether the applicant believes the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics but does not raise different questions of public health; and

(3) A concise description of the similarities and differences between the new tobacco product and the predicate tobacco product with respect to their characteristics (materials, ingredients, design, composition, heating source, or other features).

(e) *New tobacco product description.* The applicant must identify one new tobacco product in the SE Report for

comparison to one predicate tobacco product. The SE Report must describe the new tobacco product in sufficient detail to enable FDA to evaluate its characteristics. This part of the SE Report must include:

(1) A narrative description of the new tobacco product and detailed drawings or schematics of the new tobacco product, including its container closure system, illustrating all components or parts of the product. For a portioned tobacco product, the SE Report must also include a diagram illustrating all components or parts of the individual unit of use;

(2) A description and the function of each component or part of the new tobacco product, and an explanation of how each component or part is integrated into the design of the new tobacco product; and

(3) A concise overview of the process used to manufacture the new tobacco product, including the fermentation process, where applicable, with information on the type and quantity of the microbial inoculum and/or fermentation solutions. If the

manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy this provision.

(f) *Description of predicate tobacco product.* (1) The applicant must identify a predicate tobacco product that is either a grandfathered tobacco product or a tobacco product that FDA previously found to be substantially equivalent.

(2) A tobacco product to which a new tobacco product is compared must:

(i) Be in the same category and subcategory of product as the new tobacco product;

(ii) Have been either:

(A) Commercially marketed (not exclusively in a test market) in the United States as of February 15, 2007, as shown by either specific information sufficient to support this in the SE Report, including a statement that “I, (name of responsible official), confirm that the predicate tobacco product, (insert name of predicate tobacco product), was commercially marketed

other than for test marketing as of February 15, 2007”, or reference to an STN for a previous determination by FDA that the predicate product is grandfathered; or

(B) Previously determined to be substantially equivalent by FDA;

(iii) Be an individual product and not a composite of multiple products;

(iv) Not be the subject of a rescission order by FDA, as described in § 1107.50; and

(v) Not have been removed from the market at the initiative of FDA and not have been determined by judicial order to be adulterated or misbranded.

(g) *Comparison information.* The SE Report must include a comparison of the characteristics of the new tobacco product and the predicate tobacco product, as described in § 1107.19. If the new tobacco product has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (e.g., a change to product quantity), the applicant must provide comparison information related to such characteristic(s), but may certify that the other characteristics identical under paragraph (1)(2) of this section. The applicant must maintain records supporting the certification consistent with § 1107.58.

(h) *Comparative testing information.* Other than for characteristics that are identical, and for which the applicant has certified that the characteristics are identical under paragraph (1)(2) of this section, the SE Report must provide comparative testing information on the characteristics of the new and predicate tobacco products, as described in § 1107.19, except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product has the same characteristics as the predicate or does not raise different questions of public health. The testing information must:

(1) Include the test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results);

(2) Be conducted on a sufficient sample size and on test samples that reflect the finished tobacco product composition and design;

(3) State whether the same test methods were used for the new tobacco product and the predicate product, and if the methods differed, an explanation as to how the results of the different test methods can be compared; and

(4) Identify national and international standards used to test the new and predicate tobacco products and explain any deviations from the standard, or

state that no standards were used for the testing.

(i) *Statement of compliance with applicable tobacco product standards.* The SE Report must either:

(1) List and describe the action(s) taken by the applicant to comply with applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act; or

(2) State there are no applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act.

(j) *Health information summary or statement regarding availability of such information.* The SE Report must include either a health information summary or a statement that such information will be made available upon request, as provided in section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, in accord with the following:

(1) *Health information summary.* If including a health information summary with the SE Report, the applicant must provide a copy of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter (21 CFR 20.61 and 20.63); and either

(i) Provide accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product that is not contained in the SE Report; or

(ii) Provide the following statement, if true, about the new tobacco product: “Applicant does not have or know of any additional health information, including information, research or data regarding adverse health effects, about the new tobacco product that is the subject of this SE Report.”

(2) *Statement regarding availability of health information.* If the applicant chooses to make the health information available upon request, the SE Report must include the following statement, with the appropriate applicant information inserted as indicated by parenthetical text, signed by an authorized representative of the applicant, made on a separate page of the SE Report, and clearly identified as “910(a)(4) health information statement”. “I certify that, in my capacity as (*the position held in company by person required to submit the SE Report, preferably the responsible official of the applicant*) of (*company name*), I will make available, upon request, the information identified in 21 CFR 1107.18(j)(3) within 30 calendar days of a request.”

(3) *Content of health information.* The health information the applicant agrees to make available in paragraph (j)(2) of this section must be a copy of the full SE Report, excluding all research subject identifiers, trade secrets, and confidential commercial information, as defined in 21 CFR 20.61 and 21 CFR 20.63; and either.

(i) Accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product and that is not contained in the SE Report; or

(ii) The following statement, if true, about the new tobacco product.

“(Company name) does not have or know of any additional health information, including information, research or data regarding adverse health effects about the new tobacco product that is the subject of the provided SE Report.”

(4) *Requests for information.* All requests for information under paragraph (j)(2) of this section must be made in writing to the authorized representative of the applicant, whose contact information will be posted on the FDA website listing substantial equivalence determinations. The applicant must provide FDA any updated information if the contact information changes.

(5) *No modified risk violations.* To the extent information is included in the health information summary or health information provided upon request under paragraphs (j)(1) and (2) of this section that is not required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act or paragraph (j) of this section, that information must not contain a statement that would cause the tobacco product to be in violation of section 911 of the Federal Food, Drug, and Cosmetic Act upon the introduction or delivery for introduction of the proposed new product into interstate commerce.

(k) *Compliance with 21 CFR part 25.*

(1) The SE Report must include an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim of categorical exclusion. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant’s knowledge, no extraordinary circumstances exist under § 25.21.

(2) The environmental assessment must include a statement explaining whether the new tobacco product is intended to replace the predicate tobacco product once the new tobacco product receives market authorization, is intended to be a line extension of the predicate tobacco product, is intended to be introduced as an additional product by the same manufacturer, or if the new tobacco product will be introduced as an additional product but by a different manufacturer.

(1) *Certification Statement.* (1) The SE Report must contain the following certification, with the appropriate information inserted (as indicated by parenthetical text), and be signed by an authorized representative of the applicant. “I (*name of responsible official*) on behalf of (*applicant*), hereby certify that (*applicant*) will maintain all records to substantiate the accuracy of this SE Report for the period of time required in § 1107.58 and ensure that such records remain readily available to the FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant’s behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a

materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.”

(2) The SE Report must include the following certification if an applicant chooses to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco products. This certification must include the appropriate information inserted (as indicated by parenthetical text) and be signed by an authorized representative of the applicant. “I, (*name of responsible official*), on behalf of (*name of company*), certify that (*new tobacco product name*) has the following modification(s) as compared to (*name of predicate tobacco product*): (*describe modification(s), e.g., change in product quantity or change in container closure system*). Aside from these modifications, the characteristics of (*new tobacco product name*) and (*name of predicate tobacco product*) are identical. I certify that (*name of company*) understands this means there is no other modification to the materials, ingredients, design features, heating source, or any other feature. I also certify that (*name of company*) will maintain records to support the

comparison information in 21 CFR 1107.19 that substantiate the accuracy of this statement for the period of time required in 21 CFR 1107.58, and ensure that such records remain readily available to FDA upon request.”

**§ 1107.19 Comparison information.**

The SE Report must include a comparison of the characteristics of the new tobacco product to the predicate tobacco product. The comparison section of the SE Report must be organized in the following manner:

(a) *Comparison of product design.* The SE Report must include descriptions of the product designs of the new and predicate tobacco products and identify any differences. The SE Report must include, in a tabular format, a side-by-side comparison of each design parameter of the new and predicate tobacco products. For each design parameter, the target value and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) with units of measure must be provided. In addition, for each applicable design parameter, test data must be provided.

(1) *Cigarettes.* For cigarettes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 1 TO § 1107.19(a)(1)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Cigarette length (mm)</li> <li>—Cigarette circumference (mm)</li> <li>—Cigarette draw resistance (mm H<sub>2</sub>O)</li> <li>—Tobacco filler mass (mg)</li> <li>—Tobacco rod density (g/cubic centimeter (cm<sub>3</sub>))</li> <li>—Tobacco moisture (%)</li> <li>—Filter ventilation (%)</li> <li>—Tipping paper length (mm)</li>   <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>)</li> <li>—Cigarette paper base paper porosity (CU)</li> <li>—Cigarette paper band width (mm)</li> <li>—Cigarette paper band space (mm)</li> <li>—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density))</li> <li>—Filter length (mm)</li> <li>—Filter pressure drop (mm H<sub>2</sub>O)</li> </ul>	<ul style="list-style-type: none"> <li>—Puff count</li> <li>—Cigarette draw resistance (mm H<sub>2</sub>O)</li> <li>—Tobacco filler mass (mg)</li> <li>—Tobacco moisture (%)</li> <li>—Filter ventilation (%)</li> <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>)</li> <li>—Cigarette paper base paper porosity (CU)</li> <li>—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density))</li> <li>—Filter pressure drop (mm H<sub>2</sub>O)</li> </ul>

(2) *Smokeless tobacco.* For portioned and non-portioned smokeless tobacco

products, the required design parameter information to be provided for each

predicate and new tobacco product is as follows:

TABLE 2 TO § 1107.19(a)(2)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
Portioned Smokeless Tobacco Products	
<ul style="list-style-type: none"> <li>—Tobacco cut size (mm)</li> <li>—Tobacco moisture (%)</li> <li>—Portion length (mm) (if applicable)</li> <li>—Portion width (mm) (if applicable)</li> <li>—Portion mass (mg) (if applicable)</li> <li>Portion thickness (mm) (if applicable)</li> <li>Pouch paper wicking</li> <li>Pouch paper porosity (CU)</li> <li>Pouch paper basis weight (g/m<sub>2</sub>)</li> </ul>	<ul style="list-style-type: none"> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> <li>—Portion mass (mg) (if applicable).</li> <li>—Pouch paper porosity (CU).</li> <li>—Pouch paper basis weight (g/m<sub>2</sub>).</li> </ul>
Nonportioned Smokeless Tobacco Products	
<ul style="list-style-type: none"> <li>—Tobacco cut size (mm)</li> <li>—Tobacco moisture (%)</li> </ul>	<ul style="list-style-type: none"> <li>—Tobacco cut size (mm).</li> <li>—Tobacco moisture (%).</li> </ul>

(3) *Roll-your-own tobacco, rolling papers.* For roll-your-own tobacco rolling papers, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 3 TO § 1107.19(a)(3)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Paper length(mm)</li> <li>—Paper width (mm)</li> <li>—Mass per paper (mg)</li> <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>)</li> <li>—Cigarette paper base paper porosity (CU)</li> <li>—Cigarette paper band porosity (CU) (if applicable)</li> <li>—Cigarette paper band width (mm) (if applicable)</li> <li>—Cigarette paper band space (mm) (applicable)</li> </ul>	<ul style="list-style-type: none"> <li>—Mass per paper (mg).</li> <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU) (if applicable).</li> </ul>

(4) *Roll-your-own tobacco, tubes.* For roll-your-own tobacco tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 4 TO § 1107.19(a)(4)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Tube length (mm)</li> <li>—Tube circumference (mm)</li> <li>—Total mass (mg)</li> <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>)</li> <li>—Cigarette paper base paper porosity (CU)</li> <li>—Cigarette paper band porosity (CU)</li> <li>—Cigarette paper band width (mm)</li> <li>—Cigarette paper band space (mm)</li> </ul>	<ul style="list-style-type: none"> <li>—Total mass (mg).</li> <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>).</li> <li>—Cigarette paper base paper porosity (CU).</li> <li>—Cigarette paper band porosity (CU).</li> </ul>

(5) *Roll-your-own tobacco, filtered tubes.* For roll-your-own tobacco filtered tubes, the required design parameter information to be provided for each new predicate and new tobacco product is as follows:

TABLE 5 TO § 1107.19(a)(5)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Tube length (mm)</li> <li>—Tube circumference (mm)</li> <li>—Total mass (mg)</li> <li>—Tipping paper length (mm)</li> </ul>	<ul style="list-style-type: none"> <li>—Total mass (mg).</li> <li>—Filter ventilation (%).</li> <li>—Cigarette paper base paper basis weight (g/m<sub>2</sub>).</li> <li>—Cigarette paper base paper porosity (CU).</li> </ul>

TABLE 5 TO § 1107.19(a)(5)—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Filter ventilation (%)</li> <li>—Cigarette paper base paper basis weight (g/m<sup>2</sup>)</li> <li>—Cigarette paper base paper porosity (CU)</li> <li>—Cigarette paper band porosity (CU)</li> <li>—Cigarette paper band width (mm)</li> <li>—Cigarette paper band space (mm)</li> <li>—Filter length (mm)</li> <li>—Filter denier per filament (DPF)</li> <li>—Filter total denier (g/9000m)</li> <li>—Filter density (g/cm<sup>3</sup>)</li> <li>—Filter pressure drop (mm H<sub>2</sub>O)</li> </ul>	<ul style="list-style-type: none"> <li>—Cigarette paper band porosity (CU).</li> <li>—Filter denier per filament (DPF).</li> <li>—Filter total denier (g/9000m).</li> <li>—Filter density (g/cm<sup>3</sup>).</li> <li>—Filter pressure drop (mm H<sub>2</sub>O).</li> </ul>

(6) *Roll-your-own tobacco*. For roll-your-own tobacco, the required design parameter information to be provided

for each predicate and new tobacco product is as follows:

TABLE 6 TO § 1107.19(a)(6)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
<ul style="list-style-type: none"> <li>—Tobacco filler mass (mg)</li> <li>—Tobacco size (mm)</li> <li>—Tobacco moisture (%)</li> </ul>	<ul style="list-style-type: none"> <li>—Tobacco filler mass (mg).</li> <li>—Tobacco size (mm).</li> <li>—Tobacco moisture (%).</li> </ul>

(b) *Comparison of heating sources*. The SE Report must include a description of the heating source for the new and predicate tobacco products and identify any differences, or state that there is no heating source.

(c) *Comparison of product composition*. The SE Report must include descriptions of the product composition of the new and predicate tobacco products and identify any differences. The SE Report must include, in a tabular format, a side-by-side comparison of the materials and ingredients for each component or part of the new and predicate tobacco products. For each material and ingredient quantity, the target value and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part, must be provided.

(1) *Materials*. For each material in the products include:

(i) The material name and common name(s), if applicable;

(ii) The component or part of the tobacco product where the material is located;

(iii) The subcomponent or subpart where the material is located, if applicable;

(iv) The function of the material;

(v) The quantities (including ranges or means, acceptance limits) of the material(s) in each new tobacco product

and predicate tobacco product (with any specification variation, if applicable);

(vi) The specification(s) (including quality/grades, suppliers) used for the new tobacco product and predicate tobacco product (with any specification variations, if applicable); and

(vii) Any other material properties necessary to characterize the new and predicate tobacco products.

(2) *Ingredients other than tobacco*. For ingredients other than tobacco in each material and/or component or part of the product include:

(i) The International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name, if applicable;

(ii) The Chemical Abstracts Service (CAS) number(s) or FDA Unique Ingredient Identifier (UNII);

(iii) The function of the ingredient;

(iv) The quantity with the unit of measure (including ranges or means, acceptance limits) of the material(s) in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(v) The specification(s) (including purity or grade and supplier);

(vi) For complex purchased ingredients, each single chemical substance reported separately; and

(vii) Any other ingredient information necessary to characterize the new and predicate tobacco products.

(3) *Tobacco ingredients*. For tobacco include:

(i) The type, including grade and variety;

(ii) The quantity with the unit of measure (including ranges or means, acceptance limits) of tobacco in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(iii) The specification of tobacco used for the new tobacco product and the predicate tobacco product (with any specification variation, if applicable);

(iv) A description of any genetic engineering of the tobacco; and

(v) Any other information necessary to characterize the new and predicate tobacco products.

(vi) If the new tobacco product does not contain tobacco, then include a statement that the new tobacco product does not contain tobacco.

(4) *Container closure system*. A description of the container closure system for the new and predicate tobacco products, including a side-by-side quantitative comparison of the components and materials and annotated illustrations.

(d) *Comparison of other features*. The SE Report must include descriptions of any other features of the new and

predicate tobacco products, such as those described in this section, and identify any differences. If a specific feature specified in this section is not applicable to the product design, this must be stated clearly. If FDA requests a scientific justification explaining why a feature is not applicable, the applicant must provide the justification to FDA. The comparison of other features must include information on:

(1) *Constituents*. HPHCs and other constituents, as appropriate, to demonstrate that:

(i) The new tobacco product has the same characteristics as the predicate tobacco product, or

(ii) Any differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health, including:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number(s);

(D) The mean quantity and variance with unit of measure;

(E) The number of samples and measurement replicates for each sample;

(F) The analytical methods used and associated reference(s);

(G) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(H) Length of time between dates of manufacture and date(s) of testing;

(I) Storage conditions of the tobacco product before it was tested; and

(J) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria and complete data sets) for all testing performed.

(2) *Any other features*. A description and comparison of any other features of the new tobacco product and the predicate tobacco product.

(e) *Stability information*. For smokeless tobacco products and tobacco products that contain fermented tobacco, the SE Report must contain information on the stability of the new and predicate tobacco products, including the following information:

(1) A description of how the stability is indicated on the tobacco product, and an explanation as to whether the stability testing is identical for the predicate and the new tobacco product;

(2) Any known or expected impacts of the differences between the new and predicate products on the product stability. If no impact is known or expected, state that. For those products

that contain fermented tobacco, the SE Report must provide information on the fermentation processing steps, including the composition of the inoculum, with species name(s) and concentration(s); pH; temperature; moisture content; water activity; duration; and added ingredients;

(3) Detailed stability testing, including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all stability testing performed. Stability testing must be performed at the beginning (zero time), middle, and end of the expected storage time for the chemical and microbial endpoints as follows: Microbial content data including total aerobic microbial count and total yeast and mold count along with identification of detected microbiological organisms by genus and species names (if applicable); pH; moisture content; water activity; tobacco-specific nitrosamines (total, N-nitrosornicotine (NNN), 4-methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)); nitrate and nitrite levels; preservatives and microbial metabolic inhibitors (if any); and method of heat treatment or pasteurization used to reduce microbial loads;

(4) Testing information, including the storage conditions for samples retained for testing; identification of the test methods used; a statement that the testing was performed on a tobacco product in the same container closure system in which the tobacco product is intended to be marketed; and support for the expiration date (e.g., by showing that an adequate number of batches was tested);

(5) Stability testing laboratory or laboratories used and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization; and

(6) Identification of microbiological organisms by genus and species names, where applicable, and culture collection number either used during the manufacturing process and/or detected through stability testing.

(f) *Applicant's basis for substantial equivalence determination*. The applicant must state that the new tobacco product has either:

(1) The same characteristics as the predicate tobacco product and the basis for this determination, or

(2) Different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in

any of the following characteristics do not cause the new product to raise different questions of public health: Product design (§ 1107.19(a)); heating source (§ 1107.19(b)); materials and ingredients (§ 1107.19(c)); and other features (§ 1107.19(d)). In addition, to demonstrate that a new tobacco product with different characteristics is substantially equivalent, an applicant must also explain why any differences in the manufacturing process between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.19(e)).

(g) *Comparison to grandfathered product*. If the applicant is comparing the new tobacco product to a predicate tobacco product that FDA has previously found to be substantially equivalent, FDA may request that the applicant include information related to the original grandfathered tobacco product for that predicate, even if the grandfathered tobacco product is back several predicate tobacco products. FDA will request this information when necessary to ensure that any order the Agency may issue finding the new tobacco product substantially equivalent complies with section 910(a)(2)(A)(i)(I) of the Federal Food, Drug, and Cosmetic Act. FDA may need to review the first SE Report that received a finding of substantial equivalence using the grandfathered product as a predicate tobacco product in order to make this finding.

#### § 1107.20 Amendments.

(a) Except as provided in paragraphs (b) and (c) of this section, the applicant may submit an amendment to an SE Report in accordance with subpart C of this part. If an applicant chose to submit a health information summary with its SE Report under § 1107.18(j)(1), the applicant must submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.

(b) An applicant may not amend an SE Report to change the predicate tobacco product.

(c) An applicant may not amend an SE Report after FDA has closed the SE Report under § 1107.44 or it has been withdrawn under § 1107.22.

(d) In general, amendments will be reviewed in the next review cycle as described in § 1107.42.

**§ 1107.22 Withdrawal by applicant.**

(a) An applicant may at any time make a written request to withdraw an SE Report for which FDA has not issued an order. The withdrawal request must state:

(1) Whether the withdrawal is due to a health or safety concern related to the tobacco product;

(2) The submission tracking number; and

(3) The name of the new tobacco product that is the subject of the SE Report.

(b) An SE Report will be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn.

(c) The SE Report is an agency record, even if withdrawn. FDA will retain the withdrawn SE Report under Federal Agency records schedules. The availability of the withdrawn SE Report will be subject to FDA's public information regulations in § 20.45 of this chapter.

**§ 1107.24 Change in ownership of an SE Report.**

An applicant may transfer ownership of its SE Report. On or before the time of transfer, the new and former applicants are required to submit information to FDA as follows:

(a) The former applicant must sign and submit a notice to FDA that states that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. This notice must identify the name and address of the new applicant and the SE Report transferred.

(b) The new applicant must sign and submit a notice to FDA containing the following:

(1) The new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new applicant has a complete copy of the SE Report and order (if applicable), including amendments and records that are required to be kept under § 1107.58, or a request for a copy of the SE Report from FDA's files by submitting a request in accordance with 21 CFR part 20. In accordance with the Freedom of Information Act, FDA will provide a copy of the SE Report to the new applicant under the fee schedule in FDA's public information regulations in § 20.45 of this chapter; and

(4) A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

**Subpart D—FDA Review**

**§ 1107.40 Communications between FDA and applicants.**

(a) *General principles.* During the course of reviewing an SE Report, FDA may communicate with applicants about relevant matters, including scientific, medical, and procedural issues that arise during the review process. These communications may take the form of telephone conversations, letters, or emails, and will be documented in the SE Report in accordance with § 10.65 of this chapter.

(b) *Meeting.* Meetings between FDA and applicants may be held to discuss scientific and other issues. Requests for meetings will be directed to the Office of Science, and FDA will make every attempt to grant requests for meetings that involve important issues.

(c) *Acknowledgement of an SE Report.* After receiving an SE Report under § 1107.18, FDA will either refuse to accept the SE Report or issue an acknowledgement letter.

(d) *Notification of deficiencies in a SE Report submitted under § 1107.18.* FDA will make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and any additional information and data needed for the Agency's review. The applicant must also provide additional comparison information under § 1107.19 if requested by FDA.

(e) *Withdrawal of SE Report.* An SE Report will be considered withdrawn when FDA issues a notice stating that the SE Report has been withdrawn.

**§ 1107.42 Review cycles.**

(a) *Initial review cycle.* FDA intends to review the SE Report and either communicate with the applicant as described in § 1107.40 or take an action under § 1107.44 within 90 calendar days of FDA's receipt of the SE Report, or within 90 days of determining that the predicate was found to be commercially marketed in the United States as of February 15, 2007 (if applicable), whichever is later. This 90-day period is called the "initial review cycle."

(b) *Additional review cycles.* If FDA issues a deficiency notification under § 1107.40(d) during the initial review cycle, FDA will stop reviewing the SE Report until it receives a response from the applicant or the timeframe specified in the notification of deficiencies for response has elapsed. If the applicant

fails to respond within the time period provided in the notification of deficiency, FDA will issue an order denying marketing authorization under the criteria set forth in § 1107.48. If the applicant's response to the notification of deficiencies provides the information FDA requested, but FDA identifies additional deficiencies, FDA may issue an additional deficiency notification. Each response will begin a new 90-day review cycle.

(c) *Inadequate response.* If the applicant's response to FDA's deficiency notification(s) does not provide the information FDA requested, or the applicant provides information but the SE Report is still deficient, FDA will issue an order denying market authorization under the criteria set forth in § 1107.48. At any time before FDA issues an order, an applicant may make a written request to withdraw a SE Report under § 1107.22.

**§ 1107.44 FDA action on an SE Report.**

After receipt of an SE Report, FDA will:

(a) Refuse to accept the SE Report if it does not comply with § 1107.18;

(b) Request additional information as provided in § 1107.40(d);

(c) Issue a letter administratively closing the SE Report if it is not possible to make a determination on an SE Report;

(d) Issue a letter canceling the SE Report if FDA finds the SE Report was created in error;

(e) Issue an order as described in § 1107.46 finding the new tobacco product to be substantially equivalent and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act; or

(f) Issue an order as described in § 1107.48 denying marketing authorization because the new tobacco product is:

(1) Not substantially equivalent to a tobacco product commercially marketed in the United States on February 15, 2007, or

(2) Not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.

**§ 1107.46 Issuance of an order finding a new tobacco product substantially equivalent.**

If FDA finds that the information submitted in the SE Report establishes that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007, and finds that the new tobacco product is in compliance with the requirements of the Federal

Food, Drug, and Cosmetic Act, FDA will send the applicant an order authorizing marketing of the product. A marketing authorization order becomes effective on the date the order is issued.

**§ 1107.48 Issuance of an order denying marketing authorization.**

(a) *General.* FDA will issue an order that the new tobacco product cannot be marketed if FDA finds that:

(1) The information submitted in the SE Report does not establish that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007; or

(2) The new tobacco product is not in compliance with the Federal Food, Drug, and Cosmetic Act.

(b) *Basis for order.* The order will describe the basis for denying marketing authorization.

**§ 1107.50 Rescission of order.**

(a) *Grounds for rescinding a substantially equivalent order.* FDA may rescind a substantial equivalence order allowing a new tobacco product to be marketed if FDA determines that:

(1) The tobacco product for which the order has been issued:

(i) Does not have the same characteristics as the predicate tobacco product; or

(ii) Has different characteristics and there is insufficient information demonstrating that it is not appropriate to require a premarket tobacco product application under section 910(b) of the Federal Food, Drug, and Cosmetic Act because the product does not raise different questions of public health; or

(2) The SE Report (including any submitted amendments) contains an untrue statement of material fact; or

(3) Concerning a SE Report that compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent:

(i) The predicate tobacco product relied on in the SE Report has been found ineligible because its substantial equivalence SE Report (including any amendments) contains an untrue statement of material fact; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations was based, going back to the original grandfathered product, has been found ineligible because its substantial equivalence SE Report (including any amendments) contains an untrue statement of material fact; or

(4) FDA or the applicant has removed from the market, due to a health or safety concern related to the tobacco product:

(i) The predicate tobacco product on which the substantial equivalence determination is based; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations is based, going back to the original grandfathered product, if the substantial equivalence SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent.

(b) *Opportunity for a hearing.* In general, FDA will rescind an order only after notice and opportunity for a hearing under part 16 of this chapter. However, FDA may rescind a substantially equivalent order prior to notice and opportunity for a hearing under part 16 of this chapter if it finds that there is a reasonable probability that continued marketing of the tobacco product presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

**Subpart E—Miscellaneous**

**§ 1107.58 Record retention.**

Each applicant that receives an order under § 1107.46 authorizing the marketing of a new tobacco product must maintain all records required by this subpart and that support the SE Report for a substantial equivalence order. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. All records must be retained for a period of not less than 4 years from the date of the order even if such product is discontinued.

**§ 1107.60 Confidentiality.**

(a) *General.* FDA will determine the public availability of any part of an SE Report and other content related to such an SE Report under this section and part 20 of this chapter.

(b) *Confidentiality of data and information prior to an order.* Prior to issuing an order under this section:

(1) FDA will not publicly disclose the existence of an SE Report unless:

(i) The tobacco product has been introduced or delivered for introduction into interstate commerce for commercial distribution; or

(ii) The applicant has publicly disclosed or acknowledged the existence of the SE Report (as such disclosure is defined in § 20.81 of this chapter), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted the SE Report to FDA;

(2) FDA will not disclose the existence of or contents of an FDA communication with an applicant regarding its SE Report except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of or contents of that particular FDA communication.

(3) FDA will not disclose information contained in an SE Report unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information contained in an SE Report, FDA may disclose that particular information.

(c) *Disclosure of data and information after an order under § 1107.46.* After FDA issues an order under § 1107.46 finding a new tobacco product substantially equivalent, it will make the following information related to the SE Report and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the SE Report and FDA's reviews of the SE Report:

(1) All data previously disclosed to the public, as such disclosure is defined in § 20.81 of this chapter;

(2) Any protocol for a test or study, except to the extent it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter;

(3) Information and data submitted to demonstrate that the new tobacco product does not raise different questions of public health, except to the extent it is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(4) Correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, except to the extent it is shown to fall within the exemptions in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy; and

(5) In accordance with § 25.51 of the chapter (21 CFR 25.51), the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to

submit an environmental assessment under part 25 of this chapter.

(d) *Disclosure of data and information after an order under § 1107.48.* After FDA issues an order under § 1107.48 (denying marketing authorization), FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA's own initiative except to the extent the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes the tobacco product category (e.g., cigarette), tobacco product subcategory (e.g., filtered), package size, and the basis for the order denying marketing authorization.

(e) *Health information summary or statement.* Health information required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, if submitted as part of the SE Report (which includes any amendments), will be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA will make publicly available on FDA's website the

responsible official to whom a request for health information may be made.

**§ 1107.62 Electronic submission.**

(a) *Electronic format requirement.* Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The SE Report and all supporting information must be in an electronic format that FDA can process, read, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request that is legible and written in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants can send the written request to the address included on our website ([www.fda.gov/tobaccoproducts](http://www.fda.gov/tobaccoproducts)). The request must include the following information:

(1) The name and address of the applicant, list of individuals authorized

for the applicant to serve as the contact person, and contact information. If the applicant has submitted a SE Report previously, the regulatory correspondence must also include any identifying information for the previous submission; and

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the person requesting the waiver, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by an employee of the applicant who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission.* An applicant who has obtained a waiver from filing electronically must send a written SE Report through the Document Control Center to the address provided in the FDA documentation granting the waiver.

Dated: March 21, 2019.

**Scott Gottlieb,**

*Commissioner of Food and Drugs.*

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Part IV

## Small Business Administration

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Small Business Innovation Research Program and Small Business  
Technology Transfer Program Policy Directive; Notice

**SMALL BUSINESS ADMINISTRATION**

RIN 3245-AG64

**Small Business Innovation Research Program and Small Business Technology Transfer Program Policy Directive****AGENCY:** Small Business Administration.**ACTION:** Final SBIR and STTR Policy Directives.

**SUMMARY:** This document revises the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) program Policy Directives. Specifically, the Small Business Administration combines the two directives into one document, clarifies the data rights and Phase III preference afforded to SBIR and STTR small business awardees, adds definitions relating to data rights, and clarifies the benchmarks for progress towards commercialization.

**DATES:** These revisions to the SBIR/STTR Policy Directive are effective on May 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Edsel Brown, Assistant Director, Office of Innovation, at (202) 401-6365 or [technology@sba.gov](mailto:technology@sba.gov).

**SUPPLEMENTARY INFORMATION:****I. Executive Summary**

The purpose of the Small Business Innovation Research (SBIR) program is to stimulate innovation in the US economy by engaging innovative small business concerns (SBCs) in Federally-funded research and research and development (R/R&D). Similarly, the purpose of the Small Business Technology Transfer (STTR) program is to foster partnerships of ideas and technologies between innovative SBCs and research institutions through Federally-funded R/R&D. Federal agency awards to SBCs pursuant to the SBIR program and awards to SBCs for cooperative R/R&D efforts with research institutions pursuant to the STTR program assist the small business and research communities by commercializing innovative technologies.

Both programs use a phased process, uniform throughout the Federal Government, to solicit proposals and award funding agreements for R/R&D to meet stated agency needs or missions. To stimulate and foster scientific and technological innovation, including increasing commercialization of Federal R/R&D, the program follows a three phase process: Phase I, Phase II, and Phase III.

The Small Business Act (the Act) requires that the Small Business

Administration (SBA) issue a policy directive setting forth guidance to the Federal Agencies participating in the SBIR and STTR programs (Participating Agencies). The Act provides SBA with broad authority to direct Participating Agencies in the administration of the programs. The SBIR and STTR (SBIR/STTR) Policy Directives outline how agencies must generally conduct their programs. Each agency, however, can tailor its program to meet the needs of the individual agency, as long as the general principles of the program set forth in the Act and directive are followed. Therefore, when incorporating SBIR/STTR policy into agency-specific regulations and procedures, Participating Agencies may develop and apply processes needed to implement the policy effectively; however, no Participating Agency may develop and apply policies, directives, or clauses, that contradict, weaken, or conflict with the policy as stated in the directive.

SBA reviews its policy directives regularly to determine areas that need updating and further clarification. On November 7, 2014, SBA issued an advance notice of policy directive amendments and request for comments at 77 FR 66342. In this notice, SBA explained that it intended to update the directives on a regular basis and to restructure and reorganize the directives, as well as address certain policy issues related to SBIR/STTR data rights and issues related to SBIR/STTR Phase III work. SBA outlined what it believed were the issues concerning data rights and Phase III awards and requested feedback on several questions posed. SBA received over thirty comments offering recommendations and providing examples of how these issues affect SBIR/STTR companies. While the comments varied on the recommendations for specific changes they were generally in agreement that the sections of the directives relating to data rights and Phase III awards needed further clarification.

On April 7, 2016, SBA issued a notice of proposed policy directive amendments and request for comments at 81 FR 20484. In the notice, SBA proposed combining the SBIR/STTR directives into one document and revising sections of the directive to clarify SBIR/STTR data rights, issues related to SBIR/STTR Phase III work, and benchmarks toward commercialization. SBA specifically requested feedback on several of the proposed amendments, including its clarification of the Federal Government's SBIR/STTR data rights in SBIR/STTR Data, as that term is defined in the final SBIR/STTR Policy Directive,

during an SBIR/STTR protection period. More specifically, SBA requested feedback on the proposed 12-year length of the protection period, the Federal Government's Unlimited Rights in SBIR/STTR Data after the protection period, the elimination of the extension of the protection period when a subsequent, related SBIR/STTR award is made, the language added to § 8 regarding prototypes, and its proposed establishment of a time limit of 6 months for SBIR/STTR awardees to correct or add omitted markings on SBIR/STTR Data it has delivered. The notice called for a 60-day comment period, with June 6, 2016, as the deadline for comments. In response to a formal request to extend the comment period, SBA issued a notice at 81 FR 34426, extending the comment period an additional 30 days to July 6, 2016. SBA received a total of 42 comments in response to the proposed policy directive amendments, which are viewable on [Regulations.gov](http://Regulations.gov) using docket number RIN 3245-AG64.

The comments supported combining the SBIR and STTR Policy Directives and generally supported the proposed clarifications of SBIR/STTR data rights during the protection period, the clarifications of the Phase III preference requirement and process, and the majority of other proposed changes. However, several commenters strongly objected to the proposed removal of the ability to extend data rights through subsequent awards, the proposed 12-year protection period, and to the proposal that the Federal Government receives Unlimited Rights in SBIR/STTR Data after the protection period expires. These objections came primarily from the small business community. Commenters pointed out that these changes would reduce the incentive for small businesses to participate in the program and are antithetical to the small business commercialization goals of the programs.

SBA recognizes that to be efficient and effective at stimulating small business innovation, the SBIR/STTR programs must maintain the features of the programs that create strong incentives for small businesses to participate, and SBA must scrutinize whether changes to the SBIR/STTR Policy Directive are consistent with the goals of the programs. As a result, SBA is removing these specific proposed changes from this amendment and will work closely with the Participating Agencies to identify ways to address the related administrative concerns discussed in the proposed policy directive in a way that does not weaken

the data rights protection of appropriately marked SBIR/STTR Data.

Commenters also strongly objected to the inclusion of state program funding in the definition of Essentially Equivalent Work, because it would be more difficult to complement an SBIR/STTR award with additional funds from state programs. SBA recognizes the importance and advantage of leveraging SBIR/STTR awards with other sources of funds and clarifies that awardees are prohibited from accepting funds from multiple public funding sources for the same work; however, SBA supports the use of appropriate complementary funding from public funding sources for work that is not essentially equivalent.

In addition, several commenters expressed concern about the retroactivity of any revisions to the policy directive, especially as they pertain to the length of the protection period, the effective extension of data rights through subsequent awards, and the Government's rights in SBIR/STTR Data after the protection period. SBA recognizes the importance of certainty in these aspects of the programs, because they directly impact an awardee's ability to commercialize innovations derived from federal R/ R&D. As such, SBA does not intend to alter the terms or rights associated with any funding agreements that pre-date the effective date of this notice.

With this notice, SBA amends both SBIR/STTR Policy Directives. A section-by-section outline of the proposed amendments, comments received, and the final adopted approach is provided below.

## II. Amendments

### 1. Section 1—Purpose

SBA proposed to issue one directive for both programs and that all provisions in the directive apply to both the SBIR and STTR programs unless specifically noted otherwise. SBA received three comments supporting a combined policy directive for the SBIR and STTR programs and did not receive any comments in opposition. SBA is adopting this proposal and will issue one SBIR/STTR Policy Directive with provisions that apply to both programs unless specifically noted otherwise in the directive.

### 2. Section 2—Summary of Statutory Provisions

In this section, SBA proposed to delete references to prior fiscal years that were no longer relevant to the operation of the programs. In addition, SBA clarified that agencies must "obligate" a certain minimum

percentage of the agency's total extramural R/R&D obligations each fiscal year on awards to small businesses under the programs. This amendment responds to recommendations from the United States (U.S.) Government Accountability Office (GAO) in a report titled "Small Business Research Programs: More Guidance and Oversight Needed to Comply with Spending and Reporting Requirements" (GAO-14-431, available at <http://www.gao.gov/assets/670/663909.pdf>), that SBA should amend its policy directives to clarify the programs' annual spending requirements as written in the Act. SBA received one comment in opposition to this amendment, explaining that requiring Participating Agencies to obligate a certain amount per fiscal year does not recognize that some Participating Agencies have authority to appropriate funds across multiple fiscal years. In drafting this amendment, SBA considered GAO's finding that:

[a]n agency can carry over funding from one year to the next and comply with spending requirements if the agency spends the minimum required amount during the fiscal year, regardless of the year the funding was appropriated.

GAO-14-431 (Washington, DC 2014), 12. SBA believes the amendment clarifies the programs' annual spending requirement for all Participating Agencies, including those with appropriations spanning multiple fiscal years. As such, SBA is adopting the amendment as proposed.

### 3. Section 3—Definitions

SBA proposed to amend and add several terms and definitions that relate to SBIR and STTR data rights. When drafting these provisions, SBA considered the fact that the SBIR/STTR programs are unique within the Federal Government. The broad intent of the programs is to stimulate economic growth and development by supporting technological innovation through small business. Because funding is allocated by specifying a minimum spending requirement as a share of agency R/R&D, it also has the goal of meeting the mission needs of the various Participating Agencies.

The purpose of SBIR/STTR data rights is to provide an incentive for small businesses to engage in Government-funded innovative research and to support its potential commercialization. This incentive comes from the prospects for successful commercialization by the innovating small business through first-mover advantage, license or sale of the Intellectual Property, sale of the business, or sale of its related intangible

assets (intellectual capital, knowledge, innovation capacities). Legislative history of the Small Business Research and Development Enhancement Act of 1992 stated:

Section 4(e) of the bill directs SBA to modify its policy directives so as to protect small companies in three areas. The first of these is data rights. The bill directs SBA to extend an SBIR awardee's rights to data generated in the performance of its project to 4 years (as opposed to 2 years in current law). *This provision grows out of the Committee's concern that small businesses capable of producing top quality research might be reluctant to participate in the program if they fear losing control over their ideas.*

H.R. Rep. No. 554(I), 102nd Cong., 2nd Sess. 1992, 24 (emphasis added). Further, legislative history of the STTR program states the following with respect to data rights:

Lastly, of the major provisions included in this legislation, S. 856 strengthens the data rights protection for companies and research institutions that conduct STTR projects. *The change in data rights is important because it clarifies that STTR companies, like SBIR companies, retain the data rights to their technology through all phases of an STTR project.* Some agencies have been interpreting the law to mean that STTR companies only retain their data rights through phases I and II. *This clarification helps protect STTR companies from losing control of their research so that they have a greater chance of commercializing their technology themselves. This clarification is important because the Committee has learned that some agencies are providing the data to bigger contractors for development, thereby cutting out the small business. This unfortunate situation not only robs small businesses of revenues, but it also results in expensive legal costs for small businesses to protect their data rights.*

S. Rep. No. 54, 107th Cong., 1st Sess. 2001 (emphasis added). Thus, SBIR and STTR data rights give value to the work performed and thereby form an essential element of the incentive to participate in the SBIR/STTR programs and the impact of these programs.

The Act specifically directs SBA to issue directives to the Participating Agencies that provide for the retention by the SBC of rights in data generated in the performance of an SBIR or STTR award. See 15 U.S.C. 638(j)(1)(v) ("retention of rights in data generated in the performance of the contract by the small business concern;"). It also states that these rights should be provided for a minimum of four years. See 15 U.S.C. 638(j)(2)(A) and 638(p)(2)(B)(v) ("retention by a small business concern of the rights to data generated by the concern in the performance of an [SBIR or STTR] award for a period of not less than 4 years;"). The purpose of these statutory provisions is to ensure that the

SBC retains the rights to the data, and that the small business' data rights apply to all phases of the program.

In accordance with the Act, the SBIR/STTR Policy Directives currently explain that the SBC owns the data generated under the award, and that the Government has an obligation to protect the data from disclosure for at least four years. SBA recognizes that agencies with procurement and acquisition programs may face an apparent conflict between the longer term economic development goals of the programs, which depend on the ability of the participating small business to realize the commercial benefits from its new technology, and the shorter term procurement interests of the agency that focus on acquiring the technology from the SBC at a reasonable cost and controlling its development and application. In light of this potential conflict at the agency level, SBA must ensure that agency practices related to their acquisition programs do not weaken or undermine the effectiveness of the program at stimulating innovation and economic development through small business. At the same time, SBA recognizes the mutual benefits involved in administering the programs within the existing structures of the procurement agencies and has incorporated mechanisms to manage these conflicting interests. The Act requires that SBA establish sufficient provisions in the SBIR/STTR Policy Directive to ensure that SBCs retain rights in the data generated during an SBIR/STTR award.

SBA's proposed amendments were based on a review of the statute, legislative history and current directives, expertise and experience at the funding agencies, and comments received from the public. SBA proposed to update and define several new terms relating to data rights, including the following: Computer Database, Computer Programs, Computer Software, Computer Software Documentation, Data, Form Fit and Function Data, Operations Maintenance Installation or Training (OMIT) Data, Prototype, SBIR/STTR Computer Software Rights, SBIR/STTR Data, SBIR/STTR Data Rights, SBIR/STTR Protection Period, SBIR/STTR Technical Data Rights, Technical Data, and Unlimited Rights. SBA has based these definitions, to the extent practicable, on definitions used in the Federal Acquisition Regulations (FAR) and the Defense Federal Acquisition Regulations Supplement (DFARS).

With respect to specific definitions, SBA proposed to clarify the definition of the term SBIR/STTR Data by

explaining that it includes all data developed or generated in the performance of an SBIR/STTR award, including Technical Data and Computer Software. SBA notes that the definition of SBIR/STTR Data in the proposed policy directive contained the term "appropriately marked." This term was inadvertently and mistakenly included in the definition. SBIR/STTR Data is all data generated and developed in the performance of an SBIR/STTR award. The appropriate marking of such data, when delivered to the Government, provides the Government with SBIR/STTR Data Rights and obligates the Government to protect the data as SBIR/STTR Data, but it does not define the data as SBIR/STTR Data. SBA has corrected this unintentional error by removing "appropriately marked" from the definition of SBIR/STTR Data. SBA received one comment related to this definition, which supported the inclusion of Technical Data and Computer Software in the definition. As a result, SBA is adopting a revised definition of SBIR/STTR Data, which removes "appropriately marked" from the proposed definition.

SBA proposed a new definition for Intellectual Property that removed references to "ideas," "know-how," "business," "technical and research methods," "other types of intangible business assets," "all types of intangible assets either proposed or generated by an SBC as a result of its participation in the SBIR program," "designs," and "SBIR technical data." Two commenters objected to the proposed definition of this term, arguing that it unnecessarily narrows the scope of an awardee's intellectual property. The proposed definition contains a list of traditional intellectual property: Patents, copyrights, trade secrets, and mask works. SBA notes that this is not an exclusive list and although the current definition contains concepts such as "ideas" and "business," these are not typically recognized as intellectual property. SBA is adopting its proposed definition of Intellectual Property.

SBA proposed a definition of Unlimited Rights that included the right to access data that is subject to Unlimited Rights. One commenter objected to the inclusion of this right, as it is not included in the current definition of Unlimited Rights as found in the SBIR clauses of the FAR and DFARS. The commenter expressed concern that including a new right to access was an unnecessary expansion of the current definition and instead suggested that SBA adopt the current DFARS definition of Unlimited Rights. SBA agrees that it is unnecessary to

include access at this time. The definition of Unlimited Rights is meant to reflect a combination of the elements found in both the FAR and DFARS definition of that term. As such, SBA is deleting reference to "access" in this definition and adopting the rest of the definition as proposed.

With respect to prototypes, SBA proposed to amend the definition of the term Prototype to include any model, in any type of form, which is at any stage in development. SBA also proposed to clarify that the release of a prototype, other than Computer Software, to another concern, which may enable the that concern to disassemble the prototype and glean the protected data, is contrary to the purpose and intent of the Act, and the implementing SBIR/STTR Policy Directive. The release of a prototype during the protection period may provide other concerns with the Technical Data to enable them to commercialize the product and harm the SBC's ability to benefit from the technology. To address this concern, SBA proposed to add language to § 8 of the SBIR/STTR Policy Directive, notifying agencies of the potential impact of use or release during the protection period of a prototype developed under an SBIR/STTR award and requesting that agencies monitor the release and use of such prototypes.

SBA received three comments related to the proposed definition of Prototype and the clarifying language proposed for the protection of Prototypes in § 8 of the Policy Directive. Two commenters supported the proposed definition and clarification, and one commenter opposed the inclusion of "computer program embedded in hardware" in the definition. The commenter that opposed the definition noted that embedded software is already protected by SBIR/STTR Computer Software Rights and thus specifying its inclusion in the definition of prototype is confusing. Computer Software that is developed through an SBIR/STTR award is protected data, even when embedded in a prototype. The definition of prototype has historically caused confusion among small businesses and agencies, and therefore SBA is adopting the definition of Prototype, as proposed, because it clarifies that such data embedded within a prototype may receive protection as SBIR/STTR Data.

SBA also received a question regarding the proper method for marking a prototype so that it is subject to SBIR/STTR Data Rights. SBA notes that the awardee is responsible for appropriately marking the SBIR/STTR Data contained within the prototype in order to receive SBIR/STTR data rights

protection in that data consistent with how it marks any other form of SBIR/STTR Data that is not contained within a prototype.

In § 3, SBA also proposed to clarify the data rights afforded the SBC and the Federal Government in the revised definitions of SBIR/STTR Technical Data Rights, SBIR/STTR Computer Software Rights, Unlimited Rights, SBIR/STTR Protection Period, SBIR/STTR Data Rights, and SBIR/STTR Data. The current directives state that the SBC retains the rights in data for a minimum of 4 years from the date of the last deliverable. This protection period (referred to as the “SBIR/STTR Protection Period”) is extended with each subsequent, related, SBIR or STTR award. The current directives provide that the Government may not use, modify, reproduce, release, perform, display, or disclose Data or Computer Software for a minimum of 4 years. After expiration of the SBIR/STTR Protection Period, the Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties.

As currently written, it would appear from the policy directives that the Federal Government cannot use the data for any purpose during the protection period and then, once the protection period expires, may use the data for Government purposes. The SBA does not intend for the Federal Government to have no use of this data during the protection period; rather, it is intended that the Government have limited rights to use the data so that agencies can effectively evaluate the technology and administer their programs.

In clarifying the data rights protections, the SBA reviewed the FAR and DFARS, which outline distinct rights the Government generally receives when acquiring goods and services: Unlimited rights, limited rights and specifically negotiated rights (FAR) or Government purpose rights (DFARS). Pursuant to the FAR, with unlimited rights, the Government receives rights as the name implies—unlimited use of the data, whether for Government or commercial purposes. With respect to limited rights for data other than computer software and restricted rights for computer software, the FAR provides that the Government receives the right to use the data or computer software for internal purposes only and is limited as to when third parties, including support service contractors, can access and use the data. With

respect to Government purpose rights, the DFARS provides that the Federal Government receives the right to use the data for Government purposes, such as for manufacturing for Government purposes. In such cases, the Government can allow third parties to have access to the data to manufacture for Government purposes; however, the third party must sign a non-disclosure agreement and cannot use the data for its own (commercial) purposes. SBA proposed that the Federal Government receives what is referred to as SBIR/STTR Technical Data Rights to Technical Data and other Data that are not Computer Software, and SBIR/STTR Computer Software Rights to Computer Software during the SBIR/STTR Protection Period. These limited rights are intended and designed to be similar to the rights set forth in the FAR and DFARS for Data developed exclusively at private expense. This approach is appropriate for SBIR/STTR Data, as the goal of the program is to advance the commercialization efforts of the awardees, and thus SBA sought to provide rights in data that are comparable to the highest level of data rights protection provided by the Government to contractors. There are differences between how the FAR and DFARS define the Government’s rights in data developed exclusively at private expense. As a result, the definitions of SBIR/STTR Computer Software Rights and SBIR/STTR Technical Data are not exact copies of the Limited Rights Notice or Restricted Rights Notice provided in FAR 52.227–14 or the Limited Rights and Restricted Rights in DFARS 252.227–7013 and 7014. SBA uses single definitions that will apply to both civilian and defense agencies participating in the programs. The definitions are intended to reflect the main elements of the FAR and DFARS definitions of the Government’s rights in data developed exclusively at private expense, including restrictions on the rights to release and disclose that data, with the aim to encourage the awardee’s pursuit and achievement of commercialization.

SBA worked closely with agency experts in developing terminology to appropriately describe the limited rights assigned to Technical Data and Computer Software. The section of the FAR related to SBIR data rights (FAR 52.227–20) does not use specific terms to describe the limited rights assigned to SBIR Data, while the DFARS (252.227–7018) uses the terminology Limited Rights and Restricted Rights.

The SBA intends that the Government retain a right to use SBIR/STTR Data during the protection period for non-

commercial purposes and for project evaluation and assessment. SBA does not intend for the Government’s internal use of SBIR/STTR Data to interfere with, weaken, or undermine the rights or interests of the SBC in this data. Consequently, the SBA proposed that during the SBIR/STTR Protection Period, the Government is permitted some limited, or restricted, rights to use the data.

SBA received three comments that opposed the proposed definitions of SBIR/STTR Technical Data Rights and SBIR/STTR Computer Software Rights and three commenters that supported these definitions. Those in opposition expressed concerns that the proposed definitions of SBIR/STTR Technical Data Rights and SBIR/STTR Computer Software Rights would permit the Government to release SBIR/STTR technology or other proprietary data to other concerns during the SBIR/STTR Protection Period. According to the comments, this may harm the SBC’s ability to commercialize the technology and benefit from it. SBA intended and designed these rights to be similar to the rights set forth in the FAR and DFARS for data developed exclusively at private expense, with an aim to encourage the awardee’s pursuit and achievement of commercialization.

Under the proposed definitions, the Government retains a right to use SBIR/STTR Data during the protection period for non-commercial purposes and for project evaluation and assessment. Because these rights in data are comparable to the highest level of data rights protection by the Government, SBA does not believe these rights interfere with, weaken, or undermine the rights or interests of the SBC in SBIR/STTR Data. Furthermore, and specifically in response to the comments, these rights do not permit the Government to release appropriately marked SBIR/STTR Data to another concern during the protection period for purposes of a competitive Federal procurement or to advance the other concern’s commercialization goals.

One commenter expressed concern that the proposed definition of SBIR/STTR Computer Software Rights provides SBCs with rights beyond what is necessary to protect computer software developed under an SBIR/STTR funding agreement. According to the commenter, the proposed definition may inadvertently limit broad areas of technology development, because there is no prescribed method for understanding computer software as it relates to commercialization, manufacturing, or procurement purposes. In addition, one commenter

believed that the proposed definition of SBIR/STTR Computer Software Rights contradicts itself. Specifically, this commenter stated that the Government's proposed right to modify, adapt, or combine Computer Software is inconsistent with paragraph (2) of the proposed definition, which provides that the Government shall not release, disclose, or permit access to SBIR/STTR Data that is Computer Software for commercial, manufacturing, or procurement purposes without the written permission of the awardee. SBA believes that the proposed definition of SBIR/STTR Computer Software Rights addresses these concerns. The proposed definition of SBIR/STTR Computer Software Rights clarifies that during the protection period, the Government is permitted some limited, or restricted, rights to use the data for non-commercial purposes and for project evaluation and assessment. As a result, SBA is adopting its proposed definitions of SBIR/STTR Computer Software Rights and SBIR/STTR Technical Data Rights.

SBA received a comment objecting to the proposed definition of Form, Fit, and Function Data. The commenter noted that the proposed definition of Form, Fit, and Function Data is broader than the current definition in the DFARS, because it includes computer software, whereas the current DFARS definition only applies to Technical Data. SBA notes that the current FAR definition of Form, Fit, and Function Data includes computer software and that the DFARS has proposed a similar definition to apply to computer software, which has not yet been adopted, at 81 FR 39481 (June 16, 2016). The commenter expressed concern that SBA is expanding the Government's rights to data in which it does not currently have Unlimited Rights. The proposed definition of Form, Fit, and Function Data establishes a more predictable and congruous approach for all Participating Agencies and SBIR/STTR awardees that combines the key elements of Form, Fit, and Function Data as defined in both the FAR and DFARS. In light of this goal, as well as the pending proposed definition of Form, Fit, and Function Data in the DFARS and the current FAR definition of this term, SBA is adopting the proposed definition of Form, Fit, and Function Data.

SBA received one comment objecting to the proposed definition of OMIT Data. The commenter explained that the proposed definition broadens the current definition in the FAR, because it includes computer software, whereas the current FAR definition excludes

restricted computer software. According to the commenter, SBA's proposed definition notably expands the Government's rights to data in which it does not currently have Unlimited Rights. In addition, the commenter believes that the proposed definition will create uncertainty because it does not specify which types of computer software qualify as OMIT Data. The proposed definition of OMIT Data furthers the stated goal of establishing a more predictable and congruous approach to data rights across all Participating Agencies and SBIR/STTR awardees. Currently, the DFARS versions of the SBIR data rights clause provides the Government with Unlimited Rights in data generated under the award that are necessary for the installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data). In addition, SBA believes that the proposed definition of OMIT Data sufficiently specifies which types of data, including computer software data, qualify as OMIT Data. Thus, SBA is adopting the proposed definition of OMIT Data.

SBA received two comments objecting to the exclusion of Form, Fit and Function Data and OMIT Data from the definition of SBIR/STTR Data. The commenters note that excluding these types of data from the protection afforded SBIR/STTR Data is not consistent with SBA's concern regarding the disclosure of technical information contained within an SBIR/STTR developed prototype. Any appropriately marked data within a prototype receives protection under the proposed definition of SBIR/STTR Technical Data Rights or SBIR/STTR Computer Software Rights. SBA proposed that the Government receives Unlimited Rights in Form, Fit, and Function data, and OMIT data, consistent with how the FAR (52.227-14(b)(1)) and DFARS (252.227-7013(b)(1) and 252.227-7014(b)(1)) currently treat these types of data when associated with data developed exclusively at private expense. Additionally, the current FAR SBIR data rights clause (52.227-20(b)(1)) and DFARS SBIR data rights clause (252.227-7018(b)(1)) both provide the Government with unlimited rights in Form, Fit, and Function data. As a result, SBA is adopting, as proposed, the definition of SBIR/STTR Data.

The proposed definition of SBIR/STTR Data Rights contains three principal policy approaches: (1) The elimination of the extension of SBIR/STTR Data Rights for data referenced in subsequent awards; (2) a finite protection period; and, (3) the

Government receives Unlimited Rights in SBIR/STTR Data after the end of the protection period. SBA proposed to remove the provision in the directive that allows a subsequent SBIR/STTR award to effectively extend the protection period of a related, prior award, and replace it with a finite, but longer, minimum protection period. SBA noted in the proposed policy directive that the current policy of allowing extensions or resumption of data rights protection under subsequent SBIR/STTR awards creates an administrative challenge, because it is difficult for agencies to determine, prior to the disclosure of SBIR/STTR Data, whether that data is protected under a subsequent SBIR/STTR award. SBA had therefore proposed to remove the ability to extend or resume data rights protections for SBIR/STTR Data that is referenced in subsequent SBIR/STTR awards. In conjunction with, and closely related to this proposed change in policy, SBA proposed to lengthen the SBIR/STTR Protection Period to a minimum of 12 years and provide the Government with Unlimited Rights after the expiration of the protection period.

The comments received overwhelmingly opposed the proposed longer minimum protection period, the proposed removal of the extension or resumption of data rights protection, and the proposed provision of Unlimited Rights after the expiration of the protection period. Commenters noted that the current policies regarding the protection period, continuous data rights protection for SBIR/STTR Data developed under previous awards, and the Federal Government's right to use data for Government purposes after the protection period, are a necessary incentive for small business participation in the programs and are a critical incentive for funding officers to make subsequent awards to the small business that developed the technology. If SBIR/STTR Data developed under a Phase I or Phase II award cannot be protected under a subsequent Phase II or Phase III award executed after the proposed 12-year protection period, a contracting officer could give that data to another concern or large business for the non-Government entity's commercialization, because SBA proposed that the Government receive Unlimited Rights in the SBIR/STTR Data after the protection period. SBA does not intend for small businesses to lose these primary incentives for participation in the program nor to eliminate the incentives for subsequent Phase II and Phase III awards to be made

to the small business that developed the technology.

SBA proposed to eliminate the extension of SBIR/STTR Data Rights due to the administrative burden on agencies of identifying subsequent SBIR/STTR awards. One commenter expressed concern that SBA's proposal does not provide sufficient guidance as to whether SBIR/STTR Data developed under prior funding agreements would continue to receive protection beyond the proposed 12-year protection period if it had been developed into a new form. Additionally, one commenter noted that the related proposed change in the protection period would create a new administrative burden on agencies by requiring them to keep track of which SBIR/STTR Data were under the old policy and which were under the proposed policy. Commenters also noted that the administrative burden of tracking awards is an insufficient rationale to eliminate a policy that has been fundamental to small business participation in the programs. Furthermore, commenters suggested that the Government create a database to track all awards so that funding agreement officers could more easily determine which agencies have made SBIR/STTR awards and whether the data created pursuant to those awards is still within the protection period. Commenters noted that if agencies were unable to determine this information they should simply ask the prospective awardee whether it has received other SBIR/STTR awards or Phase III work. The prospective awardee has no incentive to obscure or misguide the agency regarding its award information, which may form the basis for the SBC to receive continued data rights protection of earlier developed and appropriately marked SBIR/STTR Data.

Similarly, commenters strongly objected to the proposed 12-year protection period, which was proposed to compensate for the removal of the ability to protect SBIR/STTR Data under subsequent awards. Commenters noted that the proposed protection period was not long enough if the provision that effectively extends protection through subsequent awards is removed. Several commenters suggested that if SBA adopted Unlimited Rights at the expiration of the protection period, that such period be at least 20 years to cover the timeframe necessary for many technologies to be commercialized and to mirror the length of the patent protection period.

In response to these comments and after further careful consideration of the issues, SBA has rejected two of these three elements of the proposed SBIR/

STTR Data Rights definition.

Specifically, SBA has rejected the proposed 12-year protection period and the proposed Unlimited Rights at the expiration of the protection period. SBA has decided, consistent with the proposed changes, to eliminate data rights extensions for appropriately marked SBIR/STTR Data referenced in subsequent awards. This decision was made based on several factors: (1) SBA's adoption of a considerably longer protection period than was proposed; (2) administrative ease for agencies and small business concerns to track the protection period; and (3) a greater alignment with the Government's protection period afforded to other forms of intellectual property.

SBA notes that maintaining the ability to extend the data rights and the minimum 4-year protection period are current policies that have been in place for over a decade and that many commenters supported maintaining these current policies. These commenters emphasized that the continuous protection of an awardee's SBIR/STTR Data while actively pursuing or commercializing its technology with the Federal Government, provides a significant incentive for innovative small businesses to participate in these programs. A set timeframe for data rights protection, such as the proposed twelve years, creates a firm deadline on when a technology must reach commercialization to ensure protection of its data rights during that period. As such, SBA is challenged to determine the appropriate timeframe to cover a reasonable commercialization period for every type of technology developed in the SBIR/STTR programs. The timeframe necessary for computer software commercialization, for example, varies significantly from the timeframe necessary for airline engine technology commercialization. It may be a loss to the taxpayer if such technologies are protected longer than necessary and a loss to the small business if such technologies are protected for an insufficient period of time.

SBA is adopting a 20-year protection period for appropriately marked SBIR/STTR Data and SBA intends that this much longer, finite protection period, even with the elimination of extensions to such period, will preserve the incentives for small business concerns to participate in the SBIR/STTR programs. SBA considered the comments submitted from small business concerns, advocacy groups, and participating agencies. Most small business concerns and advocacy groups

commented that the proposed 12-year protection period was insufficient to cover development for particular technologies, especially given the proposed elimination of continuous data rights extensions. Several of these commenters suggested a 20-year protection period as an alternative to the proposed 12-year protection period. SBA is confident that 20 years will be sufficient to provide data rights protection during the entire development and commercialization process for most technologies in most industries that participate in the SBIR/STTR programs. Additionally, the adoption of a 20-year protection period provides greater consistency with the 20-year protection period that the Government provides for patents issued by the U.S. Patent and Trademark Office. A 20-year protection period combined with the elimination of future extensions to SBIR/STTR data rights protection satisfies concerns raised by both small businesses and agencies regarding the administration and effectiveness of the SBIR/STTR program's data rights provisions. These changes are adopted: (1) In response to the comments received; (2) to maintain the primary incentives for small business participation in the programs; and, (3) to be consistent with the programs' statutory purpose to "assist small-business concerns to obtain the benefits of research and development performed under Government contracts or at Government expense." 15 U.S.C. 638(b)(2).

SBA acknowledges that it is challenging for the Participating Agencies to determine whether a Phase I or Phase II awardee has received subsequent Phase III work that requires an extension of their data rights protection. To remedy this challenge, SBA proposed the elimination of perpetual extensions in SBIR/STTR data rights protection. While many commenters opposed this change, given the proposed 12-year protection period, SBA is confident that by extending the protection period to 20 years, most small business concerns may achieve commercialization in that timeframe without the threat of a Government release or disclosure of SBIR/STTR Data to competitors. SBA is also clarifying that the protection period starts from the date of award, which has always been SBA's interpretation of its data rights policy, however, this is unclear in the current PD, which states that protection starts from the date of delivery of the last deliverable under an SBIR/STTR Award. This clarification will allow agencies and SBCs to know with

certainty, at the start of a Funding Agreement, the exact length of the SBIR/STTR Protection Period and can mark such data accordingly.

SBA had also proposed to change the Government's rights in SBIR/STTR Data after the SBIR/STTR Protection Period expires. Currently, the data rights clause contained in the directive allows the Government to use SBIR/STTR Data after the protection period "for Government purposes." SBA noted that the term "Government purpose" is not defined in the policy directive or FAR and therefore proposed to grant the Government Unlimited Rights in SBIR/STTR Data after the protection period has expired. Many of the public comments strongly objected to this change arguing that it could be damaging to the small business awardees and possibly to the U.S. economy and U.S. competitiveness for SBIR/STTR Data to be made globally available, with no restrictions, after the protection period has ended. One commenter also noted the concern that providing Unlimited Rights after the 12-year protection period may eliminate an awardee's copyright protection in computer software that would otherwise extend beyond the 12-year protection period. According to the commenter, FAR Part 27 generally permits awardees to claim copyright protection in computer software and gives the Government broad rights in the software, except the right to publicly distribute. If the Government receives Unlimited Rights in computer software after the 12-year protection period, it would obtain a right to sublicense software to the private sector that is otherwise disallowed under the FAR.

SBA agrees with these comments and, in response to these concerns, rejects this proposed change. We agree with the commenters that restricting the Government to retaining Government purpose rights after the protection period expires provides an important incentive for the small businesses participating in the programs and furthers the program purposes of increasing small business commercialization of innovative technology. SBA agrees that providing the Government with Unlimited Rights after the protection period would not prohibit the release of such data to international concerns of an SBIR/STTR awardee for commercialization purposes. SBA also understands the concern raised by several commenters regarding the variation in the length of time necessary to develop certain technologies. Commenters noted that medical and pharmaceutical technologies can take well over 12 years

to develop and that it is critical to have a limitation on the Government's ability to release or disclose its data during that timeframe. In response, SBA is adopting a 20-year protection period, and will restrict the Government's use of that data after the protection period expires to Government purposes.

SBA noted in the proposed policy directive, the data rights clause, as currently written, limits the Government's use and disclosure of SBIR/STTR Data after the protection period to Government use. The terms "Government use" and "Government purpose" are not defined in the directive or the FAR. While Government purpose is defined in the DFARS as essentially a non-commercial use for a Government purpose, the DFARS does not currently grant Government purpose rights in SBIR/STTR Data, either during or after the protection period. Several commenters recommended that SBA adopt the DFARS definition of Government purpose instead of the proposed Unlimited Rights or the current undefined "Government use." Commenters argued that this would provide clarity on the scope of the Government's rights, which are currently lacking in the policy directive, while appropriately limiting those rights to Government purposes.

SBA agrees with the commenters that the DFARS definition provides a limitation on the Government's use of SBIR/STTR Data after the protection period has expired and that this limitation supports small businesses' ability to continue commercialization efforts while providing the Government with greater rights to use the data. SBA notes that these rights include the ability of the Government to release the data to third-parties, subject to a non-disclosure agreement, for Federal Government manufacture or procurement. However, such releases do not allow for commercial use by third-party recipients of such data. SBA adopts the Government Purpose definition, as found at DFARS, to define the Federal Government's rights in appropriately marked SBIR/STTR Data after the protection period expires.

SBA notes that the U.S. Department of Energy (DOE) raised significant concerns that Government purpose, as defined in the DFARS, is too restrictive for DOE awards, given its unique statutory mandate and mission. DOE currently interprets "Government use" and "Government purpose" as undefined in the SBIR/STTR Policy Directives, to permit its open publication of SBIR/STTR Data once the protection period expires. This interpretation of "Government use" and

"Government purpose" is more analogous with Unlimited Rights, which permits the open disclosure and publication of SBIR/STTR Data for any purpose. DOE argues that this practice is appropriate and necessary due to its statutory authority and mandate to disclose scientific and technical information, and therefore its release and disclosure of SBIR/STTR Data generated under SBIR/STTR awards issued by DOE are subject to Unlimited Rights after the expiration of the protection period. In support of this exception to the general rule regarding the Government's rights in SBIR/STTR Data after the protection period, DOE provided detailed information about the statutory authorities that are the foundation of its research and development practices and policies. DOE notes that the Atomic Energy Act of 1954, Public Law 83-703, 42 U.S.C. 2013(b), authorizes DOE to effectuate policies by providing "a program for the dissemination of unclassified scientific and technical information and for the control, dissemination, and declassification of Restricted Data, subject to appropriate safeguards, so as to encourage scientific and industrial progress."

DOE argues that this concept was reinforced by the Energy Reorganization Act of 1974 (ERA), Public Law 93-438, which directed the DOE to enter arrangements, including for the conduct of research and development activities as long as such arrangements wouldn't prevent the dissemination of scientific or technical information. The ERA at 42 U.S.C. 5813(7), states that DOE is responsible for "creating and encouraging the development of general information to the public on all energy conservation technologies and energy sources as they become available for general use, and the Administrator . . . shall, to the extent practicable, disseminate such information through the use of mass communications." The ERA also authorizes DOE to "make arrangements (including contracts, agreements, and loans) for the conduct of research and development activities with private or public institutions or persons, including participation in joint or cooperative projects of a research, developmental, or experimental nature . . .", however, "the Administrator shall disseminate scientific, technical, and practical information acquired pursuant to this title through information programs and other appropriate means, and shall encourage the dissemination of scientific, technical, and practical information relating to energy so as to enlarge the

fund of such information and to provide that free interchange of ideas and criticism which is essential to scientific and industrial progress and public understanding.” 42 U.S.C. 5817(a) and (e).

DOE also points to the Department of Energy Organization Act of 1977 (DEOA), which states that DOE’s mission is “[t]o carry out the planning, coordination, support, and management of a balanced and comprehensive energy research and development program,” including “disseminating information resulting from such programs, including disseminating information on the commercial feasibility and use of energy from fossil, nuclear, solar, geothermal, and other energy technologies” (42 U.S.C. 7112(5)). DOE argues that under the DEOA it became responsible for establishing and maintaining “a central source of information on all energy resources and technology in furtherance of the research, development, and demonstration mission” of DOE (42 U.S.C. 5916). This information maintained by DOE shall be made available to the public, except for trade secrets or other proprietary information of another. *Id.*

SBA notes that the Government purpose definition in the DFARS, as adopted in the SBIR/STTR Policy Directive, does not permit an agency’s open publication of appropriately marked SBIR/STTR Data after the protection period. SBA understands the concerns raised by DOE on this point and provides an exception that exclusively applies to DOE, to receive Unlimited Rights in SBIR/STTR Data upon expiration of the protection period. This exception is consistent with its statutory authority, which requires the open publication of scientific and technical data. This means that once the protection period expires, DOE claims the right to openly publish the awardee’s SBIR/STTR Data to include disclosure in compliance with its statutory authority. To be clear, all other Participating Agencies must utilize the Government Purpose definition found in § 3 of the Policy Directive, which does not permit open publication of an awardee’s appropriately marked data after the protection period.

The SBA clarifies that at any time during the SBIR/STTR Protection Period, the SBIR/STTR awardee, or entity that holds the rights to the data, can provide the Government with greater rights, such as Unlimited Rights. However, the Government cannot negotiate these rights prior to an SBIR/STTR award and cannot make issuance of an SBIR/STTR award conditional

upon the relinquishment of any data rights. This is not a change from the current policy. Additionally, SBA clarifies that the Government receives Unlimited Rights in any SBIR/STTR Data that is not appropriately marked. SBA received a comment suggesting further clarification that an awardee may mark such data to indicate that it retains title to the data even though the Government receives a license for Unlimited Rights in that data. SBA agrees with this point, and notes that awardees may mark data that is subject to Unlimited Rights to demonstrate that it retains title to such data.

In addition to the amendments made to the data rights related definitions, SBA also considered whether to amend the definition of Essentially Equivalent Work to include work funded by State programs and requested public comment on whether this amendment would be appropriate. Currently, SBIR/STTR awardees may not receive duplicate funding from federal sources for Essentially Equivalent Work, but there is no explicit restriction regarding the acceptance of State program funding for work to be performed under an SBIR/STTR award. SBA proposed to include State program funding in the definition of Essentially Equivalent Work. Commenters overwhelmingly objected to the inclusion of State program funding in this definition, arguing that such funding provides important supplemental funding for SBIR/STTR-funded projects. In response to these comments, SBA is not altering the definition of Essentially Equivalent Work in these amendments. In addition, SBA added clarification to the Funding Agreement Certification and Life Cycle Certification language to specify that Essentially Equivalent Work applies to work funded by the same or any other Federal Agency, which conforms with the definition of Essentially Equivalent Work specified at § 3(m) of the SBIR/STTR Policy Directive. This amendment also addresses a recommendation from GAO, included in a report titled “Small Business Research Programs: Additional Actions Needed to Implement Fraud, Waste, and Abuse Prevention Requirements” (GAO–17–337, available at <https://www.gao.gov/products/GAO-17-337>).

Finally, SBA proposed to delete several terms and definitions that SBA believes are common and therefore do not need to be defined in a Policy Directive. Specifically, SBA deleted the following terms: Cooperative Agreement, Feasibility, Funding Agreement Officer, and Grant. SBA did not receive comments on these deletions

and has adopted these proposed changes.

#### 4. Section 4—Phased Structure of Programs

SBA proposed to move information concerning agency benchmarks towards commercialization from § 4 to § 6 because these benchmarks affect program eligibility. In addition, SBA proposed to clarify the preferences agencies must afford SBIR/STTR awardees with respect to federally-funded Phase III awards.

The Act states that a Phase III award is one that:

. . . derives from, extends, or completes efforts made under prior funding agreements under the SBIR program—

(i) in which commercial applications of SBIR-funded research or research and development are funded by non-Federal sources of capital or, for products or services intended for use by the Federal Government, by follow-on non-SBIR Federal funding awards; or

(ii) for which awards from non-SBIR Federal funding sources are used for the continuation of research or research and development that has been competitively selected using peer review or merit-based selection procedures;

15 U.S.C. 638(e)(4)(C); *see id.* § 638(e)(6)(C). The purpose of the Phase III award is to provide the small business that developed the technology in Phases I or II the opportunity to commercialize it, whether through a Federal prime or subcontract or other type of agreement.

With respect to Phase III, Congress had directed SBA to provide, for the SBIR/STTR Participating Agencies:

procedures to *ensure, to the extent practicable*, that an agency which intends to pursue research, development, or production of a technology developed by a small business concern under an SBIR program *enters into follow-on, non-SBIR funding agreements with the small business concern* for such research, development, or production;

15 U.S.C. 638(j)(2)(C) (emphasis added). Section 5001, Division E of the National Defense Authorization Act for Fiscal Year 2012, Public Law 112–81, contained the SBIR/STTR Reauthorization Act of 2011 (Reauthorization Act) which set forth several provisions relating to the SBIR and STTR programs, including a provision relating to Phase III. The Reauthorization Act emphasized that agencies are to utilize small business Phase I or II awardees for Phase III awards by adding a provision in the Act that states:

(4) PHASE III AWARDS.—*To the greatest extent practicable*, Federal agencies and

Federal prime contractors *shall issue Phase III awards relating to technology, including sole source awards, to the SBIR and STTR award recipients that developed the technology.*

15 U.S.C. 638(r)(4) (emphasis added). Section 1709, Division A of the National Defense Authorization Act for Fiscal Year 2018, Public Law 115–91, further amended section 9(r)(4) of the Small Business Act (15 U.S.C. 638(r)(4)) to now state:

(4) Competitive procedures and justification for awards.—*To the greatest extent practicable, Federal agencies and Federal prime contractors shall—*

(A) consider an award under the SBIR program or the STTR program to *satisfy the requirements under section 2304 of title 10, United States Code, and any other applicable competition requirements; and*

(B) *issue, without further justification, Phase III awards relating to technology, including sole source awards, to the SBIR and STTR award recipients that developed the technology.*

This provision addresses the concern that, at times, agencies have failed to use this authority, bypassed the small business that created the technology, and pursued the Phase III work with another business rather than actively supporting and encouraging the commercialization or further development of SBIR/STTR technology by the innovative small business that developed the technology. SBA is required by statute to report to Congress cases where agencies fail to comply with the reporting requirements and intent of the SBIR/STTR Phase III policy set forth in statute. *Id.* 638 (j)(3)(C).

Therefore, if the Federal Government is interested in pursuing further work that was performed under an SBIR or STTR award, the Government must, to the *greatest* extent practicable, pursue that work with the SBIR or STTR awardee that performed the earlier work. Notwithstanding the strong congressional mandate codified in statute, SBA continues to hear from small businesses, agencies, and trade groups that SBIR/STTR awardees do not receive Phase III awards.

As a result, SBA proposed to clarify that agencies must, to the greatest extent practicable, determine whether a requirement, solicitation or intended work either is Phase III work or includes it. If the requirement is or includes Phase III work, or if the agency is later informed that it is or includes Phase III work, SBA has clarified that the agency must document that the requirement is Phase III and then evaluate the practicability (to the greatest extent) of pursuing the required work with the SBIR/STTR awardee that conducted the

prior SBIR or STTR work. This means that the agency must first consider whether it can issue a sole source award to the Phase I or Phase II awardee. Awarding the Phase III work to the SBIR or STTR firm on a sole source basis is not practicable if, for example, the firm is no longer in business or cannot perform the work itself or with subcontractors. SBA clarifies that the decision by the agency that it is not practicable to issue a sole source award to the SBIR/STTR awardee must be documented in the contract file and a copy of that decision, including the rationale, must be provided to SBA.

SBA further proposed to clarify that if the agency determines that it cannot issue a sole source award for Phase III, then it must consider whether there are other ways to provide the preference to the SBIR/STTR awardee. Unless the agency finds that it is not practicable to pursue the Phase III work with the SBIR/STTR awardee, the agency must provide a preference and must always consider issuing a sole source award first and foremost when providing this preference.

In addition, SBA proposed to clarify the notice and appeal procedures with respect to Phase III awards or non-awards. SBA proposed that the agency must notify SBA when it does not intend to issue a Phase III award and then SBA may file a notice of intent to appeal, which may be followed by filing an appeal.

In light of the foregoing, SBA proposed to clarify § 4(c)(3) concerning the competition requirements for Phase III awards. Specifically, a Justification and Approval is no longer required by the procuring agency for a Phase III sole source award when a contracting officer determines that a technology that meets current agency requirements derives from, extends, or completes an effort made under a prior SBIR/STTR funding agreement issued competitively, and sole source awards are authorized pursuant to 15 U.S.C. 638(r)(4).

Five commenters supported the proposed changes to the Phase III competition language. No commenters opposed the proposed changes; however, SBA received two suggested changes to the proposed clarification of the phrase “to the greatest extent practicable.” Specifically, one commenter recommended that Participating Agencies consider their mission and optimal small business participation when applying “to the greatest extent practicable”. In addition, one commenter recommended that SBA revise the proposed language to clarify that Federal agencies and Federal prime contractors shall, to the greatest extent

practicable, issue Phase III awards to the SBIR and STTR award recipients for all research and development or production efforts that use SBIR/STTR technology, not only those which pursue research and development or production of the technology. SBA believes the proposed clarification sufficiently outlines the process under which agencies and Federal prime contractors comply with the statutory provision that, to the greatest extent practicable, they issue Phase III awards relating to technology, including sole source awards, to the SBIR and STTR award recipients that developed the technology. Therefore, SBA is adopting the clarification as proposed.

SBA received three comments recommending changes to SBA’s characterization of a Phase III award in the competition language, which provides that a Phase III award is an extension of prior Phase I and/or Phase II awards. The commenters expressed concern that the proposed reference to Phase III awards is incomplete and recommended that SBA revise it to include work that derives from, or completes an effort made under prior SBIR/STTR funding agreements, as provided in § 4(c) of the proposed policy directive. The language in § 4(c)(3) is sufficient and addresses the concern outlined in this comment. The Section in part states, “. . . that the project is an SBIR/STTR Phase III award that is derived from, extends or completes efforts made under prior SBIR/STTR funding agreements and is authorized pursuant to 15 U.S.C. 638(c)(4).”

In addition, one commenter suggested that SBA revise the policy directive to include bonuses or incentives to contracting officers and prime contractors that make Phase III awards. There were no suggestions for how SBA should implement these incentives. SBA believes this comment does not relate to SBA’s proposed competition language and therefore falls outside the scope of this rulemaking.

Lastly, SBA received one comment recommending that SBA not revise the policy directive to eliminate a reference to Phase III sole source authority under the FAR 6–302.5. According to the commenter, the FAR reference properly directs agencies, including those which require a Justification and Approval, to make Phase III sole source awards under the proper authority. In drafting the proposed competition language, SBA sought to establish a more uniform approach under which all Participating Agencies issue Phase III sole source awards. SBA believes the proposed language is sufficient for purposes of a

Justification and Approval, if one is deemed required by the procuring agency. Thus, SBA is adopting this language as proposed.

SBA notes that it has updated the termination date for the phase flexibility, also known as Direct to Phase II, program to September 30, 2022, or until expiration. Section 854 of the National Defense Authorization Act (NDAA) for Fiscal Year 2019, Public Law 115–232, August 13, 2018, extended the termination date for this program by amending 15 U.S.C. 638(cc).

Section 860 of the NDAA for Fiscal Year 2019 also provided authority for Participating Agencies to establish a Commercialization Assistance Pilot Program for the SBIR Program. This pilot program authorizes Participating Agencies to award a third Phase II Award to certain eligible concerns. The funds are to be used by eligible concerns for research and development activities that build an eligible entity's Phase II program and to ensure the research funded under such Phase II is rapidly progressing towards commercialization. The pilot is set to terminate on September 30, 2022.

#### 5. Section 5—Program Solicitation Process

No substantive changes were made to this section.

#### 6. Section 6—Eligibility and Application (Proposal) Requirements

SBA proposed to delete the requirement that an SBC can partner with only one research institution under the STTR program. SBA believes that a small business can partner with more than one research institution under the STTR program as long as at least 30% of the work under the award is performed by a single partnering research institution. For example, if the SBC is performing 40% of the work itself and subcontracting 30% to the single research institution, the SBC may subcontract the remaining 30% to one or more other research institutions or to another entity. SBA clarifies that in this scenario, even though an SBC may partner with research institutions that are performing less than 30% of the work, the principal investigator must be primarily employed by the SBC or the single research institution performing at least 30% of the work.

SBA proposed to move the agency benchmark performance requirements from § 4 to this section of the directive. The benchmark performance requirements, set forth in 15 U.S.C. 638(qq), are designed to ensure a minimum degree of awardee progress towards commercialization.

Specifically, the Act requires that agencies establish standards, or benchmarks, to measure: (1) The success of Phase I awardees in receiving Phase II awards, and, (2) the success of Phase I awardees in receiving Phase III awards. Agencies have established these benchmarks, which were published in the **Federal Register** and are available at [www.SBIR.gov](http://www.SBIR.gov). Any subsequent changes in the benchmarks must be approved by SBA.

SBA proposed to clarify that when SBA calculates awardee progress towards meeting the benchmark rates that each agency determines whether a Phase I applicant meets both of its benchmarks and that the details regarding agency benchmark rates and the implementation of this requirement are available to the public on [www.SBIR.gov](http://www.SBIR.gov). SBA is adopting this language as proposed. This clarification addresses a recommendation from GAO in a report titled “Small Business Research Programs: Agencies Need to Take Steps to Assess Progress Toward Commercializing Technologies” (GAO–18–207, available at <https://www.gao.gov/products/GAO-18-207>).

SBA is also clarifying the paragraph that addresses the consequence for failure to meet the benchmarks. The Small Business Act requires that SBIR/STTR awardees are ineligible for one year from the date of determination to participate in Phase I of the SBIR/STTR programs if they fail to satisfy the commercialization rate or transition rate benchmarks. 15 U.S.C. 638(qq)(1)(B) and (2)(B). SBA had interpreted the statutory consequence to mean that an SBC would be ineligible to receive an SBIR/STTR Phase I award for one year after the date of determination. SBA has reconsidered this approach and clarifies that the consequence is ineligibility to submit a proposal for a Phase I award for one year from the determination date. This clarification is consistent with the statutory consequence for failure to meet the commercialization rate or transition rate benchmarks and is more equitable for SBCs that have invested considerable time and money on proposal preparation, and that may have submitted a proposal while the SBC was compliant with the benchmarks. This clarification also increases procurement efficiency at the participating agencies by providing the ability to move forward with issuance of Phase I awards to SBCs that may have been compliant with the benchmarks at the time of proposal submission. Furthermore, this clarification addresses a recommendation from GAO in a report titled “Small Business Research Programs: Agencies Need to Take Steps

to Assess Progress Toward Commercializing Technologies” (GAO–18–207, available at <https://www.gao.gov/products/GAO-18-207>).

SBA has added language explicitly allowing participation by Tribally-owned SBIR/STTR applicants and awardees. § 9 of the Act does not prohibit participation by SBCs that are owned and controlled by Indian Tribes and it was never the intent of SBA to exclude participation of these entities in these small business innovation programs.

SBA received five comments related to the proposed changes in this section of the SBIR/STTR Policy Directive. Three of the comments supported SBA's proposed changes to this section. One comment suggested that SBA centralize the process for submitting commercialization data and should provide a way for firms to enter commercialization data. SBA notes that awardees currently have the ability to document commercialization data by updating their company profile in [www.SBIR.gov](http://www.SBIR.gov). Another commenter asked whether an SBC owned and controlled by Indian Tribes can have more than 500 employees and participate in the program. SBA believes this question is addressed in § 6(a) of the proposed policy directive and in the regulations governing the size and affiliation eligibility standards for SBIR/STTR participation. Pursuant to 13 CFR 121.702(c), an SBIR or STTR awardee, together with its Affiliates, must not have more than 500 employees. This provision governs all awardees, including those owned and controlled by Indian Tribes. SBA is adopting all of the proposed changes to § 6.

#### 7. Section 7—Program Funding Process

SBA proposed to modify the section on Dollar Value of Awards to state that SBA will review the effects of inflation on the guideline amounts annually to determine if program-wide changes in the amounts are warranted and will post the inflation amounts and any adjustments to the guideline amounts on [www.SBIR.gov](http://www.SBIR.gov). SBA received six comments related to § 7 of the SBIR/STTR Policy Directive; however, these comments did not relate to SBA's proposed change regarding inflation adjustments for the Dollar Value of Awards and therefore are considered outside the scope of this rulemaking. SBA is adopting the proposed change to § 7.

SBA is adding a new paragraph to § 7 to address the Pilot Program to Accelerate Department of Defense SBIR/STTR Awards. Section 854(b)(2) of the NDAA for Fiscal Year 2019 authorized

this pilot program to reduce the time between an SBIR/STTR solicitation to award for SBIR/STTR Awardees that receive awards from DoD. The statute directs DoD to create simplified and standardized procedures for making Phase I, Phase II, and Phase III awards with the intent to decrease the time between solicitation and award.

#### *8. Section 8—Terms of Agreement Under SBIR/STTR Awards*

SBA proposed amendments to this section to clarify the main elements of SBIR/STTR Data Rights, the SBIR/STTR Protection Period, and the terms and conditions that must be set forth in the SBIR/STTR solicitation and award as it relates to data rights. The proposed changes in this section relate to the proposed amendments to the data rights definitions contained in § 3. SBA proposed that while the Government receives SBIR/STTR Technical Data Rights and SBIR/STTR Computer Software Rights in marked SBIR/STTR Data, these rights are intended to provide a level of protection similar to that which is provided to data an agency receives and that was developed exclusively at private expense. SBA also proposed to clarify in this section that SBIR/STTR Data Rights may be negotiated; however, an agency must not make issuance of an SBIR/STTR award conditional upon the small business negotiating or consenting to negotiate modification or transfer of these rights.

§ 8 contains the proposed terms of the non-disclosure agreement that must be entered into between the Federal Government and a non-Governmental entity receiving SBIR/STTR Data in accordance with the Government's limited rights in that data. The proposed requirements are that the non-Governmental entity: (1) Understands and acknowledges the limitations on the Government's access, use, modification, reproduction, release, performance, transmission, display or disclosure as set forth in the agreement; (2) is prohibited from further releasing, disclosing, or using the data without the written permission of the SBIR/STTR awardee; (3) agrees to destroy or return to the Government all SBIR/STTR Data and all copies in its possession, at or before the time specified in the agreement, and to notify the procuring agency that all copies have been destroyed or returned; (4) is prohibited from using the data for a commercial purpose; and, (5) agrees that the SBIR/STTR Data will be accessed and used for the sole purpose of providing impartial advice or technical assistance directly to the Government. The current directives

have not required that a Federal Government contractor with access to SBIR/STTR Data enter a non-disclosure agreement; however, SBA believes this is necessary to ensure that any non-Governmental entity recipient of the data understands the limitations on the use and disclosure of SBIR/STTR Data. These requirements were based on the non-disclosure agreement requirements contained in the DFARS and FAR for contractor access to SBIR/STTR Data.

SBA received several comments urging that, prior to any release of SBIR/STTR Data outside the Government during the protection period, the entity receiving the data should be required to enter a non-disclosure agreement not only with the Government but also with the SBC that owns the data. SBA may limit the Government's rights in SBIR/STTR Data during the protection period to protect the rights in data of the small business concerns participating in the programs; however, SBA does not have the authority to require two non-Government entities to enter a non-disclosure agreement.

SBA proposed to limit the time period during which an SBIR/STTR awardee may correct or add omitted markings of SBIR/STTR Data to six months from the date the data was delivered. Currently, there is no time limit on when an awardee may correct or add omitted markings to its data. However, several of the funding agencies expressed concern that having no time limit can create administrative burdens and noted that there is a 6-month time limit to correct or add protective markings on data delivered by awardees outside the SBIR/STTR program and suggested that this requirement be imposed on SBIR/STTR awardees as well. SBA specifically requested public comment on this proposed change. Several commenters opposed the change pointing out that small business SBIR/STTR awardees may inadvertently submit data without the correct markings and that these firms should continue to be allowed to correct such a mistake at any time. SBA understands that a possible agency concern is that it may be difficult to protect SBIR/STTR data that was not properly marked when delivered and may therefore have already been released. Furthermore, SBA notes that several commenters supported the 6-month limitation and that this limitation is consistent with the timeframe that all other businesses, small and other than small, are afforded under FAR 52.227-14(f)(2) to appropriately mark their data to assert the Government's limited rights in that data. Commenters did not explain why SBIR/STTR awardees should be

provided greater latitude in terms of the marking requirements as opposed to other small businesses or other businesses regardless of size. As such, SBA adopts the proposed 6-month limitation on marking SBIR/STTR Data.

SBA proposed to include language in § 8 of the directive to reflect its concern regarding the treatment of Prototypes, other than Computer Software, that are developed under an SBIR/STTR award. SBA states that agencies should handle such Prototypes with caution to prevent the potential disclosure of the innovative technology or data developed under an SBIR/STTR award. While a prototype may not itself be considered SBIR/STTR Data because it is not "recorded information," it may be possible under certain circumstances for an agency or non-Government entity to glean protected aspects through observation or reverse engineering. SBA received several comments regarding the protection and treatment of Prototypes. Many of these comments were in support of SBA's proposed changes to add language cautioning agencies against release or disclosure of prototypes in a way that would harm SBIR/STTR awardees. SBA has adopted the proposed changes.

#### *9. Section 9—Responsibilities of SBIR/STTR Agencies and Departments*

SBA proposed to move information in Appendix X relating to the National Academy of Sciences study to this section. SBA received three comments related to § 9 of the proposed policy directive. One commenter suggested that SBA include examples of actions that amount to fraud, waste, and abuse. Another commenter stated that the reporting and annual report paragraphs do not accommodate agencies with multi-year funding, because they require that agencies report the amount of dollars obligated per fiscal year for the program. This same commenter also recommended that SBA change the term "expend" to "obligate" in § 9(e)(1). These comments do not relate to SBA's proposed reorganization of the information in Appendix X related to the National Academy of Sciences study to this section. SBA is adopting the proposed reorganization of this information.

SBA is revising the termination date for the administrative funding program to September 30, 2022, as this date was extended by section 854 of the NDAA for Fiscal Year 2019. Additionally, pursuant to changes made in the NDAA 2019, SBA has modified the paragraphs within § 9 of the Policy Directive that address technical and business assistance awards for SBIR/STTR

Awardees. The NDAA 2019 increases the maximum amount of funding that the Participating Agencies may use for such awards and expanded the potential uses for such funds. The statute also directs SBA to establish a maximum amount of assistance that may be received through these technical and business assistance awards. SBA intends to solicit input from the public as part of a published comment period prior to establishing this amount. Once SBA determines the appropriate maximum amount, such guidance will be provided on [www.sbir.gov](http://www.sbir.gov) and in the Policy Directive.

**10. Section 10—Reporting Requirements for Agencies, Applicants and Awardees**

In this section, SBA proposed to amend the title to clarify that the section relates to all reporting requirements required by statute. SBA also proposed to delete references to reports that were due in 2012 and 2014 and therefore are no longer relevant. In addition, SBA proposed to delete references to TechNet and replace them with “[www.SBIR.gov](http://www.SBIR.gov).” Any system that SBA uses to report or collect information will be on the [www.SBIR.gov](http://www.SBIR.gov) website, which is SBA’s central website for everything relating to the SBIR/STTR programs. SBA received four comments in response to its proposed changes to Section 10. Two commenters noted that there may be security risks associated with the reporting requirements for agencies, applicants, and awardees. There were no suggestions for how SBA should address these risks, and SBA did not propose changes related to the security of agency reporting. Another commenter stated that SBA should simplify and standardize all duplicate reporting of commercial data, and recommended that the National Science Foundation (NSF) be required to report on each organization receiving a grant under the Phase 0 Proof of Concept Pilot Program. Specifically, this commenter recommended that NSF report the number and names of entities that received assistance from each grant recipient, the number of SBIR proposals these entities submit, and the cost of each award per entity, recipient, and project. SBA notes that the National Institutes of Health (NIH) is the Participating Agency with authority for the Phase 0 Proof of Concept Pilot Program. SBA believes these comments fall outside the scope of the revisions and request for comments in the proposed policy directive. SBA received one comment in opposition to the proposed clarification, explaining that requiring agencies to report SBIR/STTR obligations per fiscal year does not

recognize that some Participating Agencies have authority to appropriate funds across multiple fiscal years. As stated above, SBA believes proposed revisions respond to recommendations from the GAO, directing SBA to amend its policy directives to clarify the programs’ annual spending requirements as written in the Act. Therefore, SBA is adopting the proposed changes to this section.

**11. Section 11—Responsibilities of SBA**

SBA has made no changes to this section of the Policy Directive.

**12. Section 12—Supporting Programs and Initiatives**

Section 854 of the NDAA for Fiscal Year 2019, extended the termination dates for the Commercialization Readiness Program for civilian agencies and the Phase 0 Proof of Concept Pilot Program. Both programs were extended through September 30, 2022.

**13. Appendix I: Instructions for SBIR and STTR Program Solicitation Preparation**

SBA proposed to amend the certifications that small businesses must submit prior to, upon, and after an SBIR/STTR award by combining the SBIR and STTR certifications into one and noting on the document those paragraphs that are applicable to STTR only. SBA proposed to clarify the Instructions set forth in the SBIR/STTR Policy Directive adding a specific model clause that must be reflected in all solicitations and resulting funding agreements to ensure the SBIR/STTR awardee’s data rights are protected. This model clause is intended to ensure that data rights are applied consistently throughout the Federal Government. The proposed clause sets forth the pertinent terms and definitions relating to data rights, which are also set forth and defined in § 3 of the directive and discussed in more detail in § 8 of the directive. In addition, the proposed clause in Appendix I states that the awardee small business owns the data developed or generated during the award, and clarifies that the Government has SBIR/STTR Technical Data Rights and SBIR/STTR Computer Software Rights in the data during the protection period. The clause requires the awardee to mark its protected data, which is the current practice in the Federal Government. SBA did not receive comments in response to these changes outside of the comments relevant to § s 3 and 8 of the proposed policy directive. SBA is adopting the proposed changes to Appendix I.

**13. Appendix II: SBIR/STTR Program Database.** SBA proposed to remove this appendix of database codes from the directive and will instead maintain a current list of the database codes on [www.SBIR.gov](http://www.SBIR.gov) as a ready reference for the Participating Agencies. SBA did not receive comments related to this proposed deletion and is adopting this proposed change.

**14. Appendix III: Performance Areas and Metrics.** SBA proposed to remove this list of examples of performance metrics and instead will maintain a current example list, in addition to the required metrics, as a ready reference on [www.SBIR.gov](http://www.SBIR.gov). SBA did not receive comments related to this proposed deletion and is adopting this proposed change.

Notice of Final Policy Directive for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) Programs

To: The SBIR and STTR Program

Managers

Subject: SBIR/STTR Policy Directive

**1. Purpose.** The purpose of this notice is to set forth a final SBIR/STTR Policy Directive that combines the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) program Policy Directives into one document, clarifies the data rights afforded to SBIR and STTR small business awardees, adds definitions relating to data rights, clarifies the Phase III preference to be afforded to SBIR and STTR awardees, and clarifies the benchmarks for progress towards commercialization.

**2. Authority.** The Small Business Act (15 U.S.C. 638(j) and (p)) requires the SBA Administrator to issue an SBIR and STTR program Policy Directive for the general conduct of the programs.

**3. Procurement Regulations.** It is recognized that the Federal Acquisition Regulations and agency supplemental regulations will need to be modified to conform to the requirements of this final SBIR/STTR Policy Directive. SBA’s Administrator or designee has a role in reviewing any regulatory provisions that pertain to programs authorized by the Small Business Act.

**4. Personnel Concerned.** This SBIR/STTR Policy Directive serves as guidance for all Federal Government personnel who are involved in the administration of the SBIR and STTR programs, issuance and management of funding agreements or contracts pursuant to the programs, and/or the establishment of goals for small business concerns in research or research and development acquisition or grants.

5. *Originator.* SBA's Office of Investment and Innovation.

Authorized By:

Dated: February 19, 2019.

**A. Joseph Shepard,**

*Associate Administrator for the Office of Investment and Innovation.*

Dated: March 22, 2019.

**Linda E. McMahon,**

*Administrator.*

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### 1. Purpose

(a) Sections 9(j) and 9(p) of the Small Business Act (the Act) require that the Small Business Administration (SBA) issue Policy Directives for the general conduct of the SBIR and STTR programs within the Federal Government.

(b) This Policy Directive fulfills SBA's statutory obligation to provide guidance to the participating Federal agencies for the general operation of the SBIR and STTR programs. Because most of the policy for the SBIR and STTR program is the same, SBA issues a single Policy Directive for both programs. Unless one of the programs is specifically mentioned, the term "program" or "programs" refers to both the SBIR and STTR programs. In addition, "SBIR/STTR" is used throughout to refer to both programs.

(1) The following sections pertain only to the STTR program: § 3(cc)—Definition of "Research Institution," § 7(k)—Management of the STTR Project, § 8(c)—Allocation of Intellectual Property Rights in STTR Award, and § 12(e)—Phase 0 Proof of Concept Partnership Pilot Program.

(2) The following sections pertain only to the SBIR program: § 3(b)—Definition of "Additionally Eligible State," § 3(l)—Definition of "Covered Small Business," § 4(b)(1)(ii)—Direct to Phase II Awards, § 6(a)(6)—Majority-Owned by Multiple VCOs, Hedge Funds or Private Equity Firms, § 6(b)(1)(iii)—Registration and Certifications for Proposal and Award

for Majority-Owned by Multiple VCOs, Hedge Funds or Private Equity Firms, and Appendix I—Certifications for Proposal and Award for Majority-Owned by Multiple VCOs, Hedge Funds or Private Equity Firms.

(3) Additional or modified instructions may be issued by SBA as a result of public comment or experience. With this directive, SBA fulfills the statutory requirement to simplify and standardize the program proposal, selection, contracting, compliance, and audit procedures for the programs to the extent practicable, while allowing the Participating Agencies flexibility in the operation of their individual programs. Wherever possible, SBA has attempted to reduce the paperwork and regulatory compliance burden on small business concerns (SBCs) applying to and participating in the SBIR/STTR programs, while still meeting the statutory reporting and data collection requirements.

(c) The statutory purpose of the SBIR program is to strengthen the role of innovative SBCs in Federally-funded research or research and development (R/R&D). Specific program purposes are to: (1) Stimulate technological innovation; (2) use small business to meet Federal R/R&D needs; (3) foster and encourage participation by socially and economically disadvantaged SBCs (SDBs), and by women-owned SBCs (WOSBs), in technological innovation; and, (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth.

(d) In addition to the broad goals of the SBIR program, the statutory purpose of the STTR program is to stimulate a partnership of ideas and technologies between innovative SBCs and non-profit Research Institutions. By providing awards to SBCs for cooperative R/R&D efforts with Research Institutions, the STTR program assists the U.S. small business and research communities by supporting the commercialization of innovative technologies.

(e) Federal agencies participating in the programs (Participating Agencies) are obligated to follow the guidance provided by this Policy Directive. Each Participating Agency is required to review its rules, policies, and guidance on the programs to ensure consistency with this Policy Directive and to make any necessary changes in accordance with each agency's normal procedures. This is consistent with the statutory authority provided to SBA concerning the SBIR/STTR programs.

### 2. Summary of Statutory Provisions

(a) The SBIR program is codified at § 9 of the Act, 15 U.S.C. 638. The SBIR program is authorized until September 30, 2022, or as otherwise provided in law subsequent to that date.

(b) Each Federal agency with an extramural budget for R/R&D in excess of \$100,000,000 must participate in the SBIR program and spend (obligate) a minimum percentage of their extramural R/R&D budgets (obligations) of not less than 3.2% of such budget in fiscal year 2017 and for the percentage required by statute for each fiscal year after for awards to SBCs for R/R&D under the SBIR program.

A Federal agency may exceed this minimum percentage.

(c) The STTR program is also codified at § 9 of the Act, 15 U.S.C. 638. The STTR program is authorized until September 30, 2022, or as otherwise provided in law subsequent to that date.

(d) Each Federal agency with an extramural budget for R/R&D in excess of \$1,000,000,000 must participate in the STTR program and spend (obligate) a minimum percentage of their extramural R/R&D budgets (obligations) of not less than 0.45% of such budget in fiscal year 2016 and for the percentage required by statute for each fiscal year after on awards to SBCs under the STTR program.

A Federal agency may exceed this minimum percentage.

(e) In general, each Participating Agency must make SBIR/STTR awards for R/R&D through the following uniform, three-phase process:

(1) Phase I awards to determine, insofar as possible, the scientific and technical merit and feasibility of ideas that appear to have commercial potential.

(2) Phase II awards to further develop work from Phase I that meets particular program needs and exhibits potential for commercial application.

(3) Phase III awards where commercial applications of SBIR/STTR program-funded R/R&D are funded by non-Federal sources of capital; or where products, services or further research intended for use by the Federal Government are funded by non-SBIR/STTR sources of Federal funding.

(f) Participating Agencies must report to SBA on the calculation of the agency's extramural R/R&D budget, for the purpose of determining SBIR/STTR program funding, within four months of enactment of each agency's annual Appropriations Act.

(g) The Act explains that agencies are authorized and directed to cooperate with SBA in order to carry out and

accomplish the purpose of the programs. As a result, each Participating Agency shall provide information to SBA for SBA to monitor and analyze each agency's SBIR/STTR program and to report annually to the Committee on Small Business and Entrepreneurship of the Senate and to the Committee on Small Business and the Committee on Science, Space, and Technology of the House of Representatives. For more information on the agency's reporting requirements, including the frequency for specific reporting requirements, see § 10 of the Policy Directive.

(h) SBA establishes databases and websites to collect and maintain, in a common format, information that is necessary to assist SBCs and assess the SBIR/STTR programs.

(i) SBA implements the Federal and State Technology (FAST) Partnership Program to strengthen the technological competitiveness of SBCs, to the extent that FAST is authorized by law.

(j) The competition requirements of the Armed Services Procurement Act of 1947 (10 U.S.C. 2302, *et seq.*) and the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 3101, *et seq.*) must be read in conjunction with the procurement notice publication requirements of § 8(e) of the Act (15 U.S.C. 637(e)). The following notice publication requirements of § 8(e) of the Act apply to SBIR/STTR Participating Agencies using contracts as a SBIR or STTR Funding Agreement.

(1) Any federal executive agency intending to solicit a proposal to contract for property or services valued above the amounts set forth in Federal Acquisition Regulations (FAR) § 5.101, must transmit a notice of the impending solicitation to the Government wide point of entry (GPE) for access by interested sources. See FAR § 5.201. The GPE, located at [www.fbo.gov](http://www.fbo.gov), is the single point where Government business opportunities, including synopses of proposed contract actions, solicitations, and associated information, can be accessed electronically by the public. In addition, an agency must not issue its solicitation for at least 15 days from the date of the publication of the GPE. The agency must establish a deadline for submission of proposals in response to a solicitation in accordance with FAR § 5.203.

(2) The contracting officer must generally make available through the GPE those solicitations synopsized through the GPE, including specifications and other pertinent information determined necessary by the contracting officer. See FAR § 5.102.

(3) Any executive agency awarding a contract for property or services must synopsize the award through the GPE in accordance with FAR subpart 5.3.

(4) The following are exemptions from the notice publication requirements:

(i) In the case of agencies intending to solicit Phase I proposals for contracts in excess of \$25,000, the head of the agency may exempt a particular solicitation from the notice publication requirements if that official makes a written determination, after consulting with the Administrator of the Office of Federal Procurement Policy (OFPP) and the SBA Administrator, that it is inappropriate or unreasonable to publish a notice before issuing a solicitation.

(ii) The SBIR/STTR Phase II award process.

(iii) The SBIR/STTR Phase III award process.

### 3. Definitions

(a) *Act*. The Small Business Act (15 U.S.C. 631, *et seq.*), as amended.

(b) *Additionally Eligible State*. (SBIR only) A State in which the total value of funding agreements awarded to SBCs under all agency SBIR programs is less than the total value of funding agreements awarded to SBCs in a majority of other States, as determined by SBA's Administrator in biennial fiscal years and based on the most recent statistics compiled by the Administrator.

(c) *Affiliate*. This term has the same meaning as set forth in 13 CFR part 121—Small Business Size Regulations, § 121.103, "How Does SBA Determine Affiliation?". Further information about SBA's affiliation rules and a guide on affiliation is available at [www.SBIR.gov](http://www.SBIR.gov) and [www.SBA.gov/size](http://www.SBA.gov/size).

(d) *Applicant*. The organizational entity that qualifies as an SBC at all pertinent times and that submits a contract proposal or a grant application for a funding agreement under the SBIR/STTR programs.

(e) *Awardee*. The organizational entity that receives an SBIR or STTR Phase I, Phase II, or Phase III award. An "SBIR/STTR Awardee."

(f) *Commercialization*. The process of developing products, processes, technologies, or services and the production and delivery (whether by the originating party or others) of the products, processes, technologies, or services for sale to or use by the Federal Government or commercial markets.

(g) *Computer Database*. A collection of data recorded in a form capable of being processed by a computer. The term does not include Computer Software.

(h) *Computer Programs*. A set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

(i) *Computer Software*. Computer Programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer Software does not include Computer Databases or Computer Software Documentation.

(j) *Computer Software Documentation*. Owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the Computer Software or provide instructions for using the software.

(k) *Covered Small Business Concern*. (SBIR only) A small business concern that: (1) Was not majority-owned by multiple venture capital operating companies (VCOs), hedge funds, or private equity firms on the date on which it submitted an application in response to a solicitation under the SBIR program; and (2) is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms on the date of the SBIR award.

(l) *Data*. All recorded information, regardless of the form or method of recording or the media on which it may be recorded. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(m) *Essentially Equivalent Work*. Work that is substantially the same research, which is proposed for funding in more than one contract proposal or grant application submitted to the same Federal Agency, or submitted to two or more different Federal Agencies for review and funding consideration; or work where a specific research objective and the research design for accomplishing the objective are the same or closely related to another proposal or award, regardless of the funding source.

(n) *Extramural R/R&D Budget/Obligations*. The sum of the total obligations for R/R&D minus amounts obligated during a given fiscal year for R/R&D activities by employees of a Federal Agency in or through Government-owned, Government-operated facilities. For the Agency for International Development, the "extramural budget" does not include amounts obligated solely for general

institutional support of international research centers or for grants to foreign countries. For the Department of Energy, the “extramural budget” does not include amounts obligated for atomic energy defense programs solely for weapons activities or for naval reactor programs. (See also § 7(j) of this Policy Directive for additional exemptions related to national security.)

(o) *Federal Agency*. An executive agency as defined in 5 U.S.C. 105, and a military department as defined in 5 U.S.C. 102 (Department of the Army, Department of the Navy, Department of the Air Force), except that it does not include any agency within the Intelligence Community as defined in Executive Order 12333, § 3.4(f), or its successor orders.

(p) *Federal Laboratory*. As defined in 15 U.S.C. 3703, means any laboratory, any federally funded research and development center, or any center established under 15 U.S.C. 3705 and 3707 that is owned, leased, or otherwise used by a Federal Agency and funded by the Federal Government, whether operated by the Government or by a contractor.

(q) *Form, Fit, and Function Data*. Data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For Computer Software it means data identifying source, functional characteristics, and performance requirements, but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

(r) *Funding Agreement*. Any contract, grant, or cooperative agreement entered into between any Federal Agency and any SBC for the performance of experimental, developmental, or research work, including products or services, funded in whole or in part by the Federal Government.

(s) *Government Purpose*. Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Technical Data or Computer Software for commercial purposes or authorize others to do so.

(t) *Innovation*. Something new or improved, having marketable potential, that includes the development of new technology, the refinement of existing technology, or the development of new applications for existing technology.

(u) *Intellectual Property*. The separate and distinct types of intangible property that are referred to collectively as “Intellectual Property,” including but not limited to: patents, trademarks, copyrights, trade secrets, and mask works.

(v) *Joint Venture*. See 13 CFR 121.103(h).

(w) *Key Individual*. The Principal Investigator/Project Manager and any other person named as a “key” employee in a proposal submitted in response to a Program Solicitation.

(x) *Operations, Maintenance, Installation, or Training Purposes (OMIT) Data*. Data that is necessary for operation, maintenance, installation, or training purposes (but not including detailed manufacturing or process data).

(y) *Participating Agency(ies)*. A federal agency with an SBIR or STTR program. An “SBIR/STTR Agency.”

(z) *Principal Investigator/Project Manager*. The one individual designated by the Applicant to provide the scientific and technical direction to a project supported by the Funding Agreement.

(aa) *Program Solicitation*. A formal solicitation for proposals issued by a Federal Agency that notifies the small business community of its R/R&D needs and interests in broad and selected areas, as appropriate to the agency, and requests for proposals from SBCs in response to these needs and interests.

(bb) *Prototype*. A product, material, object, system, or process, or a model thereof, that is in development, regardless of whether it is in tangible, electronic, graphic or other form, at any stage of development prior to its intended ultimate commercial production and sale. The term “Prototype” includes Computer Programs embedded in hardware or devices.

(cc) *Research Institution*. One that has a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor, and is: (1) A non-profit institution as defined in section 4(3) of the Stevenson-Wydler Technology Innovation Act of 1980 (that is, an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any

private shareholder or individual); or (2) A Federally-funded R/R&D center (FFRDC) as identified by the National Science Foundation (NSF) in accordance with the Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor regulation). A non-profit institution can include hospitals and military educational institutions, if they meet the definition above.

(dd) *Research or Research and Development (R/R&D)*. Any activity that is: (1) A systematic study directed toward greater knowledge or understanding of the subject studied; (2) a systematic study directed specifically toward applying knowledge and innovation to meet a recognized but unmet need; or (3) a systematic application of knowledge and innovation toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of Prototypes and new processes to meet specific requirements.

(ee) *SBIR/STTR Computer Software Rights*. The Federal Government’s rights during the SBIR/STTR Protection Period in specific types of SBIR/STTR Data that are Computer Software.

(1) The Federal Government may use, modify, reproduce, release, perform, display, or disclose SBIR/STTR Data that are Computer Software within the Federal Government. The Government may exercise SBIR/STTR Computer Software Rights within the Government for:

(i) Use in Government computers;  
 (ii) Modification, adaptation, or combination with other Computer Software, provided that the Data incorporated into any derivative software are subject to the rights in paragraph (ee) and that the derivative software is marked as containing SBIR/STTR Data;

(iii) Archive or backup; or  
 (iv) Distribution of a computer program to another Government agency, without further permission of the Awardee, if the Awardee is notified of the distribution and the identity of the recipient prior to the distribution, and a copy of the SBIR/STTR Computer Software Rights included in the Funding Agreement is provided to the recipient prior to the distribution. The agency in receipt of the distributed SBIR/STTR Data is subject to the data rights provisions in the SBIR/STTR Awardees SBIR/STTR funding agreement.

(2) The Government shall not release, disclose, or permit access to SBIR/STTR Data that is Computer Software for

commercial, manufacturing, or procurement purposes without the written permission of the Awardee. The Government shall not release, disclose, or permit access to SBIR/STTR Data outside the Government without the written permission of the Awardee unless:

(i) The non-Governmental entity has entered into a non-disclosure agreement with the Government that complies with the terms for such agreements outlined in § 8 of this Policy Directive; and

(ii) The release or disclosure is—

(A) To a Government support service contractor or their subcontractor in the performance of a Government support services contract for internal Government use or activities, including evaluation, diagnosis and correction of deficiencies, and adaptation, combination, or integration with other Computer Software, provided that SBIR/STTR Data incorporated into any derivative software are subject to the rights in paragraph (ee), and provided that the release is not for commercial purposes or manufacture; or

(B) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul.

(ff) *SBIR/STTR Data*. All Data developed or generated in the performance of an SBIR or STTR award, including Technical Data and Computer Software developed or generated in the performance of an SBIR or STTR award. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(gg) *SBIR/STTR Data Rights*. The Government's license rights in properly marked SBIR/STTR Data during the SBIR/STTR Protection Period as follows: SBIR/STTR Technical Data Rights in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software and SBIR/STTR Computer Software Rights in SBIR/STTR Data that is Computer Software. Upon expiration of the protection period for SBIR/STTR Data, the Government has a royalty-free license to use, and to authorize others to use on its behalf, these Data for Government Purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these Data by third parties. The Government receives Unlimited Rights in all Form, Fit, and Function Data,

OMIT Data, and unmarked SBIR/STTR Data.

(hh) *SBIR/STTR Protection Period*. The period of time during which the Government is obligated to protect SBIR/STTR Data against unauthorized use and disclosure in accordance with SBIR/STTR Data Rights. The SBIR/STTR Protection Period begins at award of an SBIR/STTR Funding Agreement and ends not less than twenty years from that date. (See § 8(b)(4) of this Policy Directive).

(ii) *SBIR/STTR Technical Data Rights*. The Federal Government's rights during the SBIR/STTR Protection Period in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software.

(1) The Government may, use, modify, reproduce, perform, display, release, or disclose SBIR/STTR Data that are Technical Data within the Federal Government; however, the Federal Government shall not use, release, or disclose the data for procurement, manufacture or commercial purposes; or release or disclose the SBIR/STTR Data outside the Government except as permitted by paragraph (2) below or by written permission of the Awardee.

(2) SBIR/STTR Data that are Technical Data may be released outside the Federal Government without any additional written permission of the Awardee only if the non-Governmental entity or foreign government has entered into a non-disclosure agreement with the Federal Government that complies with the terms for such agreements outlined in § 8 of this Policy Directive and the release is:

(i) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul;

(ii) To a Government support services contractor in the performance of a Government support services contract for internal Government use or activities, including evaluation, diagnosis or modification provided that SBIR/STTR Technical Data incorporated into any derivative Data are subject to the rights in paragraph (ii), and the release is not for commercial purposes or manufacture;

(iii) To a foreign government for purposes of information and evaluation if required to serve the interests of the U.S. Government; or

(iv) To non-Government entities or individuals for purposes of evaluation.

(jj) *Small Business Concern (SBC)*. A concern that meets the SBIR/STTR

program eligibility requirements set forth in 13 CFR 121.702, "What size and eligibility standards are applicable to the SBIR and STTR programs?"

(kk) *Socially and Economically Disadvantaged Individual*. See 13 CFR 124.103 and 124.104.

(ll) *Socially and Economically Disadvantaged SBC (SDB)*. See 13 CFR part 124, subpart B.

(mm) *Student/Faculty-owned SBC*. A small business that is majority-owned by a faculty member or a student of an institution of higher education as defined in 20 U.S.C. 1001.

(nn) *Subcontract*. Any agreement, other than one involving an employer-employee relationship, entered into by an Awardee of a Funding Agreement calling for supplies or services for the performance of the original Funding Agreement.

(oo) *Technology Development Program*.

(1) the Established Program to Stimulate Competitive Research (EPSCoR) of the National Science Foundation as established under 42 U.S.C. 1862g;

(2) the Defense Established Program to Stimulate Competitive Research (DEPSCoR) of the Department of Defense;

(3) the Established Program to Stimulate Competitive Research (EPSCoR) of the Department of Energy;

(4) the Established Program to Stimulate Competitive Research (EPSCoR) of the Environmental Protection Agency;

(5) the Established Program to Stimulate Competitive Research (EPSCoR) of the National Aeronautics and Space Administration;

(6) the Institutional Development Award (IDeA) Program of the National Institutes of Health; and

(7) the Agriculture and Food Research Initiative (AFRI) of the Department of Agriculture.

(pp) *Technical Data*. Recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including Computer Software Documentation and Computer Databases). The term does not include Computer Software or financial, administrative, cost or pricing, or management information, or other data incidental to contract or grant administration. The term includes recorded Data of a scientific or technical nature that is included in Computer Databases.

(qq) *United States*. The 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the

Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

(rr) *Unlimited Rights*. The Federal Government's rights to use, modify, prepare derivative works, reproduce, release, perform, display, disclose, or distribute Data in whole or in part, in any manner and for any purpose whatsoever, and to have or authorize others to do so.

(ss) *Women-Owned SBC (WOSB)*. An SBC that is at least 51% owned by one or more women, or in the case of any publicly owned business, at least 51% of the stock is owned by women, and women control the management and daily business operations.

#### 4. Phased Structure of Programs

The SBIR/STTR programs employ a phased process, uniform throughout the Federal Government, of soliciting proposals and awarding Funding Agreements for R/R&D, production, services, or any combination, to meet stated agency needs or missions. Agencies must issue SBIR/STTR awards pursuant to competitive and merit-based selection procedures. Agencies may not use investment of venture capital or investment from hedge funds or private equity firms as a criterion for an SBIR/STTR award. Although cost sharing or matching funds cannot be required for Phase I or Phase II awards, agencies may require a small business to have matching funds for certain special awards (e.g., to reduce the gap between a Phase II and Phase III award). In order to stimulate and foster scientific and technological innovation, including increasing Commercialization of Federal R/R&D, the program must follow a uniform competitive process of the following three phases, unless an exception applies:

(a) *Phase I*. Phase I involves a solicitation of contract proposals or grant applications to conduct feasibility-related experimental or theoretical R/R&D related to described agency requirements. These requirements, as defined by agency topics contained in a solicitation, may be general or narrow in scope, depending on the needs of the agency. The object of this phase is to determine the scientific and technical merit and feasibility of the proposed effort and the quality of performance of the SBC with a relatively small agency investment before consideration of further Federal support in Phase II.

(1) Several different proposed solutions to a given problem may be funded.

(2) Proposals will be evaluated on a competitive basis. Agency criteria used to evaluate SBIR/STTR proposals must give consideration to the scientific and

technical merit and feasibility of the proposal along with its potential for Commercialization. Considerations may also include program balance with respect to market or technological risk or critical agency requirements.

(3) Agency benchmarks for progress towards Commercialization must be met to be eligible to participate in Phase I of the program. See § 6(a) of this Policy Directive for a description of this Phase I eligibility requirement.

(4) Agencies may require the submission of a Phase II proposal as a deliverable item under Phase I.

##### (b) *Phase II*.

(1) The object of Phase II is to continue the R/R&D effort from the completed Phase I. Unless an exception set forth in paragraphs (i) or (ii) below applies, only SBIR/STTR Phase I Awardees are eligible to participate in Phase II.

(i) A Federal Agency may issue an SBIR Phase II award to an STTR Phase I Awardee to further develop the work performed under the STTR Phase I award. Similarly, an agency may issue an STTR Phase II award to an SBIR Phase I Awardee to further develop the work performed under the SBIR Phase I award. The agency must base its decision upon the results of work performed under the Phase I award and the scientific and technical merit and commercial potential of the Phase II proposal. The Phase I Awardee must meet the eligibility and program requirements of the Phase II program from which it will receive the award in order to receive the Phase II award.

(ii) [SBIR only] The National Institutes of Health (NIH), Department of Defense (DoD) and the Department of Education (DoEd) may issue a Phase II SBIR award to an SBC that did not receive a Phase I SBIR or STTR award for that R/R&D. Prior to such an award, the heads of those agencies, or designees, must issue a written determination that the small business has demonstrated the scientific and technical merit and feasibility of the ideas that appear to have commercial potential. The determination must be submitted to SBA prior to issuing the Phase II award. This pilot program shall terminate on September 30, 2022, unless otherwise extended.

(iii) [SBIR only] A Federal Agency must implement a Commercialization Assistance Pilot Program, under which SBCs may apply to receive a third Phase II award to carry out further commercialization activities. Awards made under this pilot program may not exceed the limitation on size of awards and shall be disbursed during the performance of a Phase II award. The

funds awarded may only be used for research and development activities that build on the Phase II work and ensure it is rapidly progressing towards commercialization. The head of each Participating Agency may be allocated not more than 5 percent of the funds allocated to the SBIR program of that agency for the purpose of making awards under this pilot program. SBA may determine a covered agency has a sufficiently similar program, and thus is not required to implement the pilot program.

(A) To be selected to receive an award under this pilot program, an SBC shall submit to the Participating Agency implementing the program an application at such time, in such manner, and containing such information as the Participating Agency may require, including:

a. An updated Phase II commercialization plan; and  
b. The source and amount of the required matching funding.

(B) Eligible SBCs has received:

a. A Phase II award under an SBIR program; and  
b. A Sequential Phase II ("second Phase II") from the covered agency to which the SBC is apply for a third Phase II award under this pilot program.

(C) Matching funding from an eligible third party is required. The matching amount (excluding any fees collected by the SBC) must be equal to the amount of the award. SBCs may not use funding from ineligible sources to meet the matching requirement.

a. Eligible third-party investors include:

i. a SBC other than the eligible SBC;  
ii. venture capital firms;  
iii. individual investors;  
iv. a non-SBIR federal, state, or local government;  
v. or any combination thereof.

b. Ineligible sources include:

i. The eligible SBC's internal research and development funds;  
ii. Funding in forms other than cash (such as in-kind or other tangible assets);

iii. Funding from the owners of the eligible SBC, or the family members or affiliates of such owners; or  
iv. Funding attained through loans or other forms of debt obligations.

(D) Agencies shall consider the following when making awards under this pilot program:

a. The extent to which such award could aid the eligible entity in commercializing the research funded under the eligible entity's Phase II program;

b. Whether the updated Phase II commercialization plan provides a

sound approach for establishing technical feasibility that could lead to commercialization of such research;

c. Whether the proposed activities to be conducted under such updated Phase II commercialization plan further improve the likelihood that such research will provide societal benefits;

d. Whether the small business concern has progressed satisfactorily in Phase II to justify receipt of a subsequent Phase II SBIR award;

e. The expectations of the eligible third-party investor that provides matching funding; and

f. The likelihood that the proposed activities to be conducted under such updated Phase II commercialization plan using matching funding provided by such eligible third-party investor will lead to commercial and societal benefit.

(E) The pilot under this subsection shall terminate on September 30, 2022, unless otherwise extended.

(2) Funding must be based upon the results of work performed under a Phase I award and the scientific and technical merit, feasibility and commercial potential of the Phase II proposal. Phase II awards may not necessarily complete the total research and development that may be required to satisfy commercial or Federal needs beyond the SBIR/STTR program. The Phase II Funding Agreement with the Awardee may, at the discretion of the awarding agency, establish the procedures applicable to Phase III agreements. The Government is not obligated to fund any specific Phase II proposal.

(3) The SBIR/STTR Phase II award decision process requires, among other things, consideration of a proposal's commercial potential. Commercial potential includes the potential to transition the technology to private sector applications, Government applications, or Government contractor applications. Commercial potential in a Phase II proposal may be evidenced by:

(i) the SBC's record of successfully commercializing SBIR/STTR or other research;

(ii) the existence of Phase II funding commitments from private sector or other non-SBIR/STTR funding sources;

(iii) the existence of Phase III, follow-on commitments for the subject of the research; and

(iv) other indicators of commercial potential of the idea.

(4) Agencies may not use an invitation, pre-screening, or pre-selection process for eligibility for Phase II. Agencies must note in each solicitation that all Phase I Awardees may apply for a Phase II award and provide guidance on the procedure for doing so.

(5) A Phase II Awardee may receive one additional, sequential Phase II award to continue the work of an initial Phase II award. The additional, sequential Phase II award has the same guideline amounts and limits as an initial Phase II award.

(6) Agencies may offer special SBIR/STTR awards, such as Phase IIB awards, that supplement or extend Phase II awards. For example, some agencies administer Phase IIB awards that differ from the base Phase II in that they require third party matching of the SBIR/STTR funds. Each such supplemental award must be linked to a base Phase II award (the initial Phase II, or the second sequential Phase II award). Any SBIR/STTR funds used for such special or supplementary awards are aggregated with the amount of the base Phase II to determine the size of that Phase II award. Therefore, while there is no limit on the number of such special/supplementary awards, there is a limit on the total amount of SBIR/STTR funds that can be administered through them—the amounts of these awards count towards the size of the initial Phase II or the sequential Phase II, each of which has a guideline amount of \$1 million and a limit of \$1.5 million. (Note that Phase IIB awards under the NIH SBIR program are administered as second, sequential Phase II awards, not supplemental awards. As such, they are base Phase II awards and subject to the Phase II guideline amounts and limits of \$1 million and \$1.5 million).

(7) A concern that has received a Phase I award from an agency may receive a subsequent Phase II award from another agency if each agency makes a written determination that the topics of the relevant awards are the same and both agencies report the awards to the SBA including a reference to the related Phase I award and initial Phase II award if applicable.

(8) Agencies may issue Phase II awards for testing and evaluation of products, services, or technologies for use in technical or weapons systems.

(c) *Phase III.* Phase III refers to work that derives from, extends, or completes an effort made under prior SBIR/STTR Funding Agreements, but is funded by sources other than the SBIR/STTR programs. Phase III work is typically oriented towards Commercialization of SBIR/STTR research or technology, including through further R/R&D work.

(1) *Phase III work:* Each of the following types of activity constitutes SBIR/STTR Phase III work:

(i) Commercial application (including R/R&D, testing and evaluation of products, services or technologies for use in technical or weapons systems) of

SBIR/STTR-funded R/R&D that is financed by non-Federal sources of capital. (Note: The guidance in this Policy Directive regarding SBIR/STTR Phase III pertains to the non-SBIR/STTR federally-funded work described in (ii) and (iii) below. It does not address private agreements an SBIR/STTR firm may make in the Commercialization of its technology, except for a subcontract to a Federal contract that may be a Phase III.).

(ii) SBIR/STTR-derived products or services intended for use by the Federal Government, funded by non-SBIR/STTR sources of Federal funding.

(iii) Continuation of SBIR/STTR work, funded by non-SBIR/STTR sources of Federal funding including R/R&D.

(2) *Data Rights.* A Phase III award is, by its nature an SBIR/STTR award, has SBIR/STTR status, and must include SBIR/STTR Data Rights protection. If an SBIR/STTR Awardee receives a Funding Agreement (whether competed, direct award, sole sourced or a subcontract) for work that derives from, extends, or completes efforts made under prior SBIR/STTR Funding Agreements, then the Funding Agreement for the new work must have all SBIR/STTR Phase III status and SBIR/STTR Data Rights.

(3) *Competition Requirement.* The competitions for SBIR/STTR Phase I and Phase II awards satisfy any competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. An agency that wishes to fund an SBIR/STTR Phase III award, which is an extension of prior Phase I and/or Phase II awards, is not required to conduct another competition for the Phase III award in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR/STTR award, it is sufficient to state for purposes of a Justification and Approval, if one is deemed required by the agency, that the project is an SBIR/STTR Phase III award that is derived from, extends, or completes efforts made under prior SBIR/STTR Funding Agreements and is authorized pursuant to 15 U.S.C. 638(r)(4). Further justification is not needed.

(4) Phase III work may be for products, production, services, R/R&D, or any such combination.

(5) There is no limit on the number, duration, type, or dollar value of Phase III awards made to a business concern. There is no limit on the time that may elapse between a Phase I or Phase II award and Phase III award, or between a Phase III award and any subsequent Phase III award. A Federal Agency may enter into a Phase III SBIR/STTR

agreement at any time with a Phase II Awardee. Similarly, a Federal Agency may enter into a Phase III SBIR/STTR agreement at any time with a Phase I Awardee. A subcontract to a Federally-funded prime contract may be a Phase III award.

(6) *Size*. The small business size limits for Phase I and Phase II awards do not apply to Phase III awards.

(7) *Special acquisition requirement*. Agencies or their Government-owned, contractor-operated (GOCO) facilities, Federally-funded research and development centers (FFRDCs), or Government prime contractors that pursue R/R&D or production of technology developed under the SBIR/STTR program shall issue Phase III awards relating to the technology, including sole source awards, to the Awardee that developed the technology under an SBIR/STTR award, to the greatest extent practicable, consistent with an Agency's mission and optimal small business participation.

(i) *Implementing the requirement*. In recognition of the prior merit-based competitive selection of, and subsequent commitment of agency funds to SBIR/STTR Awardees and the broad intent of the program to promote the commercial success of these small businesses, Agencies must make a good faith effort to negotiate with such Awardees regarding the performance of the new, related, work and to issue Phase III awards for the work. When implementing this requirement, the agency will evaluate the work for consistency with its documented mission requirements and must consider the practicality of pursuing the work with the Awardee through a direct follow-on award by performing market research to determine whether the firm is available, capable, and willing to perform the work. If an award is made, the Agency must identify the funding agreement as an SBIR or STTR Phase III. The Agency must act in ways consistent with the Congressional intent to support the Commercialization of an SBIR/STTR-developed technology by the SBIR/STTR Awardee, and all parties must proceed along these steps in good faith.

(ii) *Sole Source Awards*. If pursuing the Phase III work with the Awardee is found to be practicable, the agency must award a non-competitive contract to the firm.

(iii) *Other Preference*. If pursuing Phase III work with the Awardee on a sole source/non-competitive basis does not meet the requirements set forth in the above sections regarding availability, practicality and capability, the Agency must document the file and

provide a copy of the decision, including the rationale, to the SBA. The agency should also use other means of affording preference for the Phase III work, especially when the request is for a large acquisition program, which may not be best suited for an SBIR/STTR Award. Examples include reference to the SBIR/STTR Awardee's brand-name as a required deliverable in the request for proposals, requiring the prime awardee to use evaluation factors favoring subcontracting to SBIR/STTR concerns, or providing other incentives to the prime contractor for utilizing SBIR/STTR Awardees as subcontractors, as referenced in 15 U.S.C. 638(y).

(iv) *Agency Notice of Intent to Award*. An agency, or its GOCOs or FFRDCs, that intends to pursue Phase III work (which includes R/R&D, production, services, or any combination thereof of a technology developed under an SBIR/STTR award), with an entity other than the Phase I or Phase II SBIR/STTR Awardee, must notify SBA in writing prior to such an award. This notification must include, at a minimum:

(A) The steps the agency has taken to fulfill the special acquisition requirement (e.g., a good faith effort to make the award to the SBIR/STTR Awardee).

(B) The reasons why a follow-on Funding Agreement with the SBIR/STTR Awardee is not practicable (e.g., SBIR/STTR Awardee was not willing or interested in the work, not capable of doing the work or functioning as a prime and subcontracting the work, or no longer in business).

(C) The identity of the entity with which the agency intends to make an award to perform the research, development, or production; the type of Funding Agreement to be used; and the amounts of the agreement.

(v) *SBA Notice of Intent to Appeal*. SBA may appeal a decision by an agency (or its GOCOs or FFRDCs) to pursue Phase III work with a business concern other than the SBIR/STTR Awardee that developed the technology to the head of the contracting activity.

(A) If SBA receives an agency's notice of intent to make an award under (iv) above, SBA may file a notice of intent to appeal with the Funding Agreement officer no later than 5 business days after receiving the agency's notice of intent to make award.

(B) If an agency is pursuing work that SBA has determined is Phase III work and has not complied with either of the reporting requirements above, SBA may notify the agency at any time of its intent to appeal the decision to proceed with the work. SBA makes such determinations based on all information

it receives, including information presented directly to SBA by an SBIR/STTR Awardee.

(vi) *Suspension of Work*. Upon receipt of SBA's notice of intent to appeal, the Funding Agreement officer must suspend further action on the funding agreement until the head of the contracting activity issues a written decision on the appeal. The Funding Agreement officer may proceed with award only if he or she determines in writing that the award must be made to protect the public interest. The Funding Agreement officer must include a statement of the facts justifying such a determination and provide a copy of its determination to SBA.

(vii) *SBA Appeal*. Within 10 business days of SBA's notice of intent to appeal, SBA may file a formal appeal with the head of the agency. SBA's appeal will state with specificity SBA's conclusion that the agency's obligation to make a Phase III award "to the greatest extent practicable" has not been fulfilled.

(viii) *Agency Decision*. Within 30 business days of receiving SBA's appeal, the head of the agency's contracting or grant-making activity must render a written decision setting forth the basis of his or her determination. During this period, the agency should consult with SBA and review any case-specific information SBA believes to be pertinent.

(ix) *SBA Case Report to Congress*. SBA notifies Congress of all instances in which an agency pursued Phase III R/R&D, or production of a technology developed under an SBIR/STTR award, with a business or entity other than the SBIR/STTR Awardee. SBA will notify Congress of such instances, of any agency determination or decision justifying an award to other than the Phase III SBIR/STTR Awardee, and of any SBA appeals of agency decisions under this section.

## 5. Program Solicitation Process

(a) *Topics/Subtopics*. At least annually, each agency must issue a Program Solicitation that sets forth a substantial number of R/R&D topics and subtopic areas consistent with stated agency needs or missions. Agencies may decide to issue joint solicitations. Both the list of topics and the description of the topics and subtopics must be sufficiently comprehensive to provide a wide range of opportunities for SBCs to participate in the agency R/R&D programs. Topics and subtopics must emphasize the need for proposals with advanced concepts to meet specific agency R/R&D needs. Each topic and subtopic must describe the needs in sufficient detail to assist in providing

on-target responses, but cannot involve detailed specifications to prescribed solutions of the problems.

(b) *Master Schedule*. The Act requires issuance of SBIR/STTR Phase I Program Solicitations in accordance with a Master Schedule coordinated between SBA and the SBIR/STTR Participating Agency. The SBA office responsible for coordination is: Office of Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416. Phone: (202) 205-6450. Fax: (202) 205-7754. Email: [technology@sba.gov](mailto:technology@sba.gov). Website: [www.SBIR.gov](http://www.SBIR.gov).

(c) *Coordination of Agency Schedules*. For maximum participation by interested SBCs, it is important that the planning, scheduling and coordination of agency Program Solicitation release dates be completed as early as practicable to coincide with the commencement of the fiscal year on October 1. Bunching of agency Program Solicitation release and closing dates may prohibit SBCs from preparation and timely submission of proposals for more than one SBIR/STTR project. SBA's coordination of agency schedules minimizes the bunching of proposed release and closing dates. SBIR/STTR Agencies may elect to publish multiple Program Solicitations within a given fiscal year to facilitate in-house agency proposal review and evaluation scheduling.

(d) *Posting of Master Schedule*. SBA posts a Master Schedule of release dates of Program Solicitations with links to the Participating Agency websites. For more information see § 10(c) of this Policy Directive.

(e) *Simplified, Standardized, and Timely SBIR/STTR Program Solicitations*

(1) The Act requires simplified, standardized and timely SBIR/STTR solicitations and for agencies to use a "uniform process" minimizing the regulatory burden for SBCs. Therefore, the instructions in Appendix I to this Policy Directive purposely depart from normal Government solicitation format and requirements. Furthermore, while all of Appendix I is applicable for Phase I and Phase II procurements, only § 5(d) of Appendix I is applicable for Phase III procurements.

(2) Agencies must update [www.SBIR.gov](http://www.SBIR.gov) with information on each solicitation and modification no later than 5 days after the date of release of the solicitation or modification to the public. This must include any update to the website link for the Program Solicitation.

(3) SBA does not intend that the SBIR/STTR Program Solicitation replace or be used as a substitute for unsolicited

proposals for R/R&D awards to SBCs. In addition, the SBIR/STTR Program Solicitation procedures do not prohibit other agency R/R&D actions with SBCs that are carried on in accordance with applicable statutory or regulatory authorizations.

## 6. Eligibility and Application (Proposal Requirements)

### (a) Eligibility Requirements

(1) *Certification*. To receive SBIR/STTR funds, each Awardee of a Phase I or Phase II award must qualify as an SBC at the time of award and at any other time set forth in SBA's regulations at 13 CFR 121.701-121.705. Each Phase I and Phase II Awardee must submit a certification stating that it meets the size, ownership and other requirements of the SBIR or STTR program at the time of award, and at any other time set forth in SBA's regulations at 13 CFR 121.701-121.705. SBA's size regulations for the SBIR/STTR program require that an Awardee be directly owned and controlled by individuals or SBCs; however, SBA is clarifying that an SBC directly owned and controlled by an Indian Tribe or by another SBC that is directly owned and controlled by an Indian Tribe may also be eligible to participate in the SBIR/STTR programs.

(2) *Performance of Work Requirements*. For SBIR Phase I, a minimum of two-thirds of the research or analytical effort must be performed by the Awardee. For SBIR Phase II, a minimum of one-half of the research or analytical effort must be performed by the Awardee. Occasionally, deviations from these SBIR requirements may occur, and must be approved in writing by the Funding Agreement officer after consultation with the agency SBIR/STTR program manager/coordinator. For STTR Phase I and Phase II, not less than 40 percent of the R/R&D work must be performed by the SBC, and not less than 30 percent of the R/R&D work must be performed by a partnering Research Institution. Deviations from these STTR requirements are not allowed, as the performance of work requirements are specified in statute at 15 U.S.C. 638(e). An agency can measure this research or analytical effort using the total award dollars or labor hours, and must explain to the small business in the solicitation how it will be measured.

(3) *Employment of the Principal Investigator/Project Manager*. For both Phase I and Phase II, the primary employment of the Principal Investigator/Project Manager must be with the SBC (or the Research Institution—STTR only) at the time of award and during the conduct of the proposed project. Primary employment

means that more than one-half of the Principal Investigator/Project Manager's employment time is spent in the employ of the SBC (or Research Institution—STTR only). This precludes full-time employment with another organization. Occasionally, deviations from this requirement may occur, and must be approved in writing by the Funding Agreement officer after consultation with the agency SBIR/STTR program manager/coordinator. Further, an SBC may replace the Principal Investigator/Project Manager on an SBIR/STTR Phase I or Phase II award, subject to approval in writing by the Funding Agreement officer. For purposes of the SBIR/STTR programs, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the Awardee. This is consistent with SBA's size regulations, 13 CFR 121.106, "How Does SBA Calculate Number of Employees?"

(4) *Location of the work*. For both Phase I and Phase II, the R/R&D work must be performed in the United States. However, based on a rare and unique circumstance, agencies may approve a particular portion of the R/R&D work to be performed or obtained in a country outside of the United States, for example, if a supply or material or other item or project requirement is not available in the United States. The Funding Agreement officer must approve each such specific condition in writing.

(5) *Novated/Successor in Interested/ Revised Funding Agreements*. An SBIR/STTR Awardee may include, and SBIR/STTR work may be performed by, those identified via a "novated" or "successor in interest" or similarly-revised Funding Agreement. For example, in order to receive a Phase III award, the Awardee must have either received a prior Phase I or Phase II award or been novated a Phase I or Phase II award (or received a revised Phase I or Phase II award if a grant or cooperative grant). In addition, an SBIR/STTR Awardee may include those that have merely reorganized with the same key staff (e.g., reorganized from a partnership to an LLC), regardless of whether they have been assigned a different tax identification number. In cases where there is a novation or similarly revised Funding Agreement, agencies may require the original Awardee to relinquish its rights and interests in an SBIR/STTR project in favor of another Applicant as a condition for that Applicant's eligibility to participate in the programs for that project.

(6) *Majority-Owned by Multiple VCOs, Hedge Funds or Private Equity*

*Firms [SBIR Only]*. NIH, Department of Energy (DOE), and NSF may each award not more than 25% of the agency's SBIR funds to SBCs that are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms through competitive, merit-based procedures that are open to all eligible SBCs. Any other SBIR Participating Agency may award not more than 15% of the agency's SBIR funds to such SBCs. SBIR agencies may or may not choose to utilize this funding option. A table listing the agencies that are currently using this authority can be found at [www.SBIR.gov](http://www.SBIR.gov). This authority is set forth in 13 CFR 121.701–121.705.

(i) Before permitting participation in the SBIR program by SBCs that are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms, the SBIR agency must submit a written determination to SBA, the Senate Committee on Small Business and Entrepreneurship, the House Committee on Small Business and the House Committee on Science, Space, and Technology at least 30 calendar days before it begins making awards to such SBCs. The determination must be made by the head of the Federal Agency or designee and explain how awards to such SBCs in the SBIR program will:

(A) induce additional venture capital, hedge fund, or private equity firm funding of small business innovations;

(B) substantially contribute to the mission of the Federal Agency;

(C) address a demonstrated need for public research; and

(D) otherwise fulfill the capital needs of SBCs for additional financing for SBIR projects.

(ii) The SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms must register with SBA in the Company Registry Database, at [www.SBIR.gov](http://www.SBIR.gov), prior to the date it submits an application for an SBIR award.

(iii) The SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms must submit a certification with its proposal stating, among other things, that it has registered with SBA.

(iv) Any agency that makes an award under this paragraph during a fiscal year shall collect and submit to SBA data relating to the number and dollar amount of Phase I awards, Phase II awards, and any other category of awards by the Federal Agency under the SBIR program during that fiscal year. See § 10 of this Policy Directive for the specific reporting requirements.

(v) If an agency awards more than the percentage of the funds authorized under § 6(a)(6) of this Policy Directive, the agency shall transfer from its non-SBIR and non-STTR R/R&D funds to the agency's SBIR funds any amount that is in excess of the authorized amount. The agency must transfer the funds not later than 180 days after the date on which the Federal Agency made the award that exceeded the authorized amount.

(vi) If a Federal Agency makes an award under a solicitation more than 9 months after the date on which the period for submitting applications under the solicitation ends, a Covered Small Business Concern is eligible to receive the award, without regard to whether it meets the eligibility requirements of the program for a SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms, if the Covered Small Business Concern meets all other requirements for such an award. In addition, the agency must transfer from its non-SBIR and non-STTR R/R&D funds to the agency's SBIR funds any amount that is so awarded to a Covered Small Business Concern. The funds must be transferred not later than 90 days after the date on which the Federal Agency makes the award.

*(7) Agency Benchmarks for Progress Towards Commercialization.*

(i) Before making a new Phase I award to an Awardee that has won multiple prior SBIR/STTR awards, each agency must establish benchmarks for progress towards Commercialization and determine whether an Applicant meets those benchmarks. Agencies must apply two SBA-approved performance standards (benchmarks) addressing an Awardee's progress towards Commercialization: A Phase II Transition Rate that sets a minimum required rate of progress from Phase I to Phase II over a specified period, and a Commercialization Rate Benchmark that sets the minimum Commercialization results an Awardee must have realized from its prior SBIR/STTR awards over a specified period.

(ii) If an Awardee fails to meet either of the benchmarks, that Awardee is not eligible to submit a proposal for a new Phase I award (and any new Phase II award issued pursuant to paragraph 4(b)(1)(ii)) for a period of one year from the time of the determination.

(iii) For each benchmark, agencies establish a threshold number of prior awards an Awardee must have won for the benchmark requirement to be applied.

(iv) Using information received from the agencies and from SBIR/STTR Awardees, SBA identifies the

companies that have won more than the threshold number of awards and calculates the Phase II Transition Rates and Commercialization Rates for those companies. The results of this assessment are used by each agency to determine if a company fails to meet a benchmark rate and is therefore not eligible to submit a proposal for a new Phase I award. Agencies must notify SBA of any applications denied because of failure to meet the benchmarks. The assessment results and eligibility determinations are not made public. Participating Agencies and SBA officials view the results through secure user accounts on [www.SBIR.gov](http://www.SBIR.gov). Each participating company can view the results of the last benchmark assessment once it has created a Small Business User account on [www.SBIR.gov](http://www.SBIR.gov). If an Awardee believes its assessment was made in error, it may provide SBA with the pertinent award information and request a reassessment.

(v) Current details of these requirements and the implementation processes used by the agencies are posted on [www.SBIR.gov](http://www.SBIR.gov) under the "Performance Benchmark Requirements" tab. Changes to these benchmarks requirements and procedures become effective when posted on [www.SBIR.gov](http://www.SBIR.gov). Agencies must submit any changes to the benchmarks to SBA for prior approval. If approved, SBA will publish the benchmarks and allow for public comment at least 60 days before becoming effective.

*(b) Proposal (Application) Requirements.*

*(1) Registration and Certifications for Proposal and Award.*

(i) Each Applicant must register in SBA's Company Registry Database at [www.SBIR.gov](http://www.SBIR.gov) (see Appendix I) and submit a .pdf document of the registration and any required certifications with its application if the information cannot be transmitted automatically to the SBIR/STTR Agencies from [www.SBIR.gov](http://www.SBIR.gov). Applicants must have updated their information on the Company Registry no more than 6 months prior to the date of a proposal submission.

(ii) Agencies may request the SBIR/STTR Applicant to submit a certification at the time of submission of the application, which requires the Applicant to state that it intends to meet the size, ownership and other requirements of the SBIR/STTR program at the time of award of the Funding Agreement, if selected for award. See Appendix I for the required text of the certification.

(iii) [SBIR Only] For those agencies using the authority under § 6(a)(6) of this Policy Directive, each Phase I and Phase II Applicant that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms is required to submit a specific certification with its SBIR application to the SBIR agency (see Appendix I for the required text of the certification).

(2) *Commercialization Plan.* A succinct commercialization plan must be included with each proposal for an SBIR/STTR Phase II award. Elements of a commercialization plan will include the following, as applicable:

(i) *Company information.* Focused objectives/core competencies; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience, and subsequent Commercialization.

(ii) *Customer and Competition.* Clear description of key technology objectives, current competition, and advantages compared to competing products or services; description of hurdles to acceptance of the innovation.

(iii) *Market.* Milestones, target dates, analyses of market size, and estimated market share after first year sales and after 5 years; explanation of plan to obtain market share.

(iv) *Intellectual Property.* Patent status, technology lead, trade secrets or other demonstration of a plan to achieve sufficient protection to realize the commercialization stage and attain at least a temporal competitive advantage.

(v) *Financing.* Plans for securing necessary funding in Phase III.

(vi) *Assistance and mentoring.* Plans for securing needed technical or business assistance through mentoring, partnering, or through arrangements with State assistance programs, SBDCs, Federally-funded research laboratories, Manufacturing Extension Partnership centers, or other assistance providers.

(3) *Data Collection.* Each Phase I and II Applicant is required to provide information on [www.SBIR.gov](http://www.SBIR.gov) (see Appendix II as posted on [www.SBIR.gov](http://www.SBIR.gov)). Each SBC applying for a Phase II award is required to update its Commercialization information on [www.SBIR.gov](http://www.SBIR.gov) for all of its prior Phase II awards (see Appendix II as posted on [www.SBIR.gov](http://www.SBIR.gov)).

## 7. Program Funding Process

Because the Act requires a “simplified, standardized funding process,” specific attention must be given to the following areas of SBIR/STTR program administration:

(a) *Timely Receipt of Proposals.* Program Solicitations must establish proposal submission dates for Phase I and may establish proposal submission dates for Phase II. However, agencies may also negotiate mutually acceptable Phase II proposal submission dates with individual Phase I Awardees.

(b) *Review of Proposals.* SBA encourages participating agencies to use their routine review processes for SBIR/STTR proposals whether internal or external evaluation is used. A more limited review process may be used for Phase I due to the larger number of proposals anticipated. Where appropriate, “peer” reviews external to the agency are authorized by the Act. SBA cautions participating agencies that all review procedures must be designed to minimize any possible conflict of interest as it pertains to Applicant proprietary Data. The standardized SBIR/STTR solicitation advises potential Applicants that proposals may be subject to an established external review process and that the Applicant may include company designated proprietary information in its proposal.

(c) *Selection of Awardees.*

(1) *Time Period for Decision on Proposals.*

(i) NIH and NSF must issue a notice to an Applicant for each proposal submitted stating whether it was recommended or not for award no more than one year after the closing date of the solicitation. NIH and NSF agencies should issue the award no more than 15 months after the closing date of the solicitation. Pursuant to paragraph (iii) below, NIH and NSF are encouraged to reduce these timeframes.

(ii) All other Participating Agencies must issue a notice to an Applicant for each proposal submitted stating whether it was recommended or not for award no more than 90 calendar days after the closing date of the solicitation. Agencies should issue the award no more than 180 calendar days after the closing date of the solicitation.

(iii) Agencies are encouraged to develop programs or measures to reduce the time periods between the close of a Phase I solicitation/receipt of a Phase II application and notification to the Applicant as well as the time to the issuance of the Phase I and Phase II awards. As appropriate, agencies should adopt accelerated proposal, evaluation, and selection procedures designed to address the gap in funding these competitive awards to meet or reduce the timeframes set forth above. With respect to Phase II awards, SBA recognizes that Phase II arrangements between the agency and Applicant may require more detailed negotiation to

establish terms acceptable to both parties; however, agencies must not sacrifice the R/R&D momentum created under Phase I by engaging in unnecessarily protracted Phase II proceedings.

(iv) *Request for Waiver.*

(A) If the agency determines that it requires additional time between the solicitation closing date and the notification of recommendation for award, it must submit a written request for an extension to SBA. The written request must specify the number of additional calendar days needed to issue the notice for a specific Applicant and the reasons for the extension. If an agency believes it will not meet the timeframes for an entire solicitation, the request for an extension must state how many awards will not meet the statutory timeframes, as well as the number of additional calendar days needed to issue the notice and the reasons for the extension. The written request must be submitted to SBA at least 10 business days prior to when the agency must issue its notice to the Applicant. Agencies must send their written request to: Office of Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416. Phone: (202) 205-6450. Fax: (202) 205-7754. Email: [technology@sba.gov](mailto:technology@sba.gov).

(B) SBA will respond to the request for an extension within 5 business days, as practicable. SBA may authorize an agency to issue the notice up to 90 calendar days after the timeframes set forth in paragraphs (c)(1)(i) and (ii).

(C) Even if SBA grants an extension of time, the SBIR/STTR Participating Agency is required to develop programs or measures to reduce the time periods between the close of a Phase I solicitation/receipt of a Phase II application and notification to the Applicant as well as the time to the issuance of the Phase I and Phase II awards as set forth in paragraph (c)(1)(iii) above.

(D) If an SBIR/STTR Participating Agency does not receive an extension of time, it may still proceed with the award to the small business and must complete the requirements in (C) above.

(2) *Standardized Solicitation.*

(i) The standardized SBIR/STTR Program Solicitation must advise Phase I Applicants that additional information may be requested by the awarding agency to evidence Awardee responsibility for project completion and advise Applicants of the proposal evaluation criteria for Phase I and Phase II.

(ii) The SBIR/STTR Agency will provide information to each Phase I

Awardee considered for a Phase II award regarding Phase II proposal submissions, reviews, and selections.

(d) *Essentially Equivalent Work.* SBIR/STTR Applicants often submit duplicate or similar proposals to more than one soliciting agency when the announcement or solicitation appears to involve similar topics or requirements. However, Essentially Equivalent Work must not be funded in the SBIR/STTR or other Federal Agency programs, unless an exception to this rule applies. Agencies must verify with the Applicant that this is the case by requiring them to certify at the time of award and during the life cycle of the award that they do not have Essentially Equivalent Work funded by the same or another Federal Agency.

(e) *Cost Sharing.* Cost sharing can serve the mutual interests of the Participating Agencies and certain program Awardees by assuring the efficient use of available resources. Cost sharing on SBIR/STTR projects cannot be required of Applicants for Phase I and Phase II, although it may be encouraged for any phase award. However, cost sharing cannot be an evaluation factor in the review of Phase I proposals. The standardized SBIR/STTR Program Solicitation (Appendix I) will provide information to prospective program Applicants concerning cost sharing.

(f) *Payment Schedules and Cost Principles.*

(1) SBIR/STTR Awardees may be paid under an applicable, authorized progress payment procedure or in accordance with a negotiated/definitized price and payment schedule. Advance payments are optional and may be made under appropriate law. In all cases, agencies must make payment to recipients under SBIR/STTR Funding Agreements in full, subject to audit, on or before the last day of the 12-month period beginning on the date of completion of the Funding Agreement requirements.

(2) All SBIR/STTR Funding Agreements must use, as appropriate, current cost principles and procedures authorized for use by the Participating Agencies. By the time of award, agencies must have informed each Awardee of the applicable Federal regulations and procedures that refer to the costs that, generally, are allowable under Funding Agreements.

(3) Agencies must, to the extent possible, shorten the amount of time between the notice of an award under the SBIR/STTR program and the subsequent release of funding with respect to the award.

(i) Pilot Program to Accelerate Department of Defense SBIR and STTR Awards

(A) The Under Secretary of Defense for Research and Engineering, acting through the Director of Defense Procurement and Acquisition Policy of the Department of Defense, shall establish a pilot program to reduce the time for awards under the SBIR and STTR programs of the Department of Defense, under which the Department of Defense shall—

(i) develop simplified and standardized procedures and model contracts throughout the Department of Defense for Phase I, Phase II, and Phase III SBIR awards;

(ii) for Phase I SBIR and STTR awards, reduce the amount of time between solicitation closure and award;

(iii) for Phase II SBIR and STTR awards, reduce the amount of time between the end of a Phase I award and the start of the Phase II award;

(iv) for Phase II SBIR and STTR awards that skip Phase I, reduce the amount of time between solicitation closure and award;

(v) for sequential Phase II SBIR and STTR awards, reduce the amount of time between Phase II awards; and

(vi) reduce the award times described in clauses (ii), (iii), (iv), and (v) to be as close to 90 days as possible.

(B) In carrying out the pilot program under subparagraph (A), the Director of Defense Procurement and Acquisition Policy of the Department of Defense shall consult with the Director of the Office of Small Business Programs of the Department of Defense.

(C) The pilot program under subparagraph (A) shall terminate on September 30, 2022.

(g) *Funding Agreement Types and Fee or Profit.* Statutory requirements for uniformity and standardization require consistency in application of SBIR/STTR program provisions among SBIR/STTR Agencies. However, consistency must allow for flexibility by the various agencies in their missions and needs as well as the wide variance in funds required to be devoted to SBIR/STTR programs in the agencies. The following instructions meet all of these requirements:

(1) *Funding Agreement.* The type of Funding Agreement (contract, grant, or cooperative agreement) is determined by the awarding agency, but must be consistent with 31 U.S.C. 6301–6308. Contracting agencies may issue SBIR/STTR awards as fixed price contracts (including firm fixed price, fixed price incentive or fixed price level of effort contracts) or cost type contracts, consistent with the FAR and agency

supplemental acquisition regulations. In some cases, small businesses seek progress payments, which may be appropriate under fixed-price R&D contracts and are a form of contract financing for firm-fixed-price contracts. However, for certain agencies, in order to qualify for progress payments or an incentive type contract, the small business's accounting system would have to be audited, which can delay award, unless the contractor has an already approved accounting system. Therefore, SBIR/STTR Agencies should consider using partial payments methods or on a deliverable item basis or consider other available options to work with the SBIR/STTR Awardee.

(2) *Fee or Profit.* Except as expressly excluded or limited by statute, awarding agencies must provide for a reasonable fee or profit on SBIR/STTR Funding Agreements, consistent with normal profit margins provided to profit-making firms for R&D work.

(h) *Periods of Performance and Extensions.*

(1) In keeping with the legislative intent to make a large number of relatively small awards, modification of Funding Agreements to increase the dollar amount should be kept to a minimum, except for options in original Phase I or II awards.

(2) *Phase I.* Period of performance normally should not exceed 6 months for SBIR or 1 year for STTR. However, agencies may provide a longer performance period where appropriate for a particular project.

(3) *Phase II.* Period of performance under Phase II is a subject of negotiation between the Awardee and the issuing Participating Agency. The duration of Phase II normally should not exceed 2 years. However, agencies may provide a longer performance period where appropriate for a particular project.

(i) *Dollar Value of Awards.*

(1) Generally, a Phase I award (including modifications) may not exceed \$150,000 and a Phase II award (including modifications) may not exceed \$1,000,000. Agencies may issue an award that exceeds these award guideline amounts by no more than 50%.

(2) SBA reviews these amounts every year for the effects of inflation and posts these inflation effects and any resulting adjustments on [www.SBIR.gov](http://www.SBIR.gov). Adjusted guidelines are effective for all solicitations issued on or after the date of the adjustment, and may be used by agencies to amend the solicitation and other program literature. Agencies have the discretion to issue awards for less than the guidelines.

(3) There is no dollar limit associated with Phase III SBIR/STTR awards.

(4) Agencies may request a waiver to exceed the award guideline amounts established in paragraph (i)(1) by more than 50% for a specific topic. Agencies must submit this request for a waiver to SBA prior to release of the solicitation, contract award, or modification to the award for the topic. The request for a waiver must explain and provide evidence that the limitations on award size will interfere with the ability of the agency to fulfill its research mission through the SBIR or STTR program; that the agency will minimize, to the maximum extent practicable, the number of awards that exceed the guideline amounts by more than 50%; and that research costs for the topic area differ significantly from those in other areas. After review of the agency's justification, SBA may grant the waiver for the agency to exceed the award guidelines by more than 50% for a specific topic. SBA will issue a decision on the request within 10 business days. The waiver will be in effect for one fiscal year.

(5) Agencies must maintain information on all awards exceeding the guidelines set forth in paragraph (i)(1), including the amount of the award, a justification for exceeding the guidelines for each award, the identity and location of the Awardee, whether the Awardee has received any venture capital, hedge fund, or private equity firm investment, and whether the Awardee is majority-owned by multiple VCOs, hedge funds, or private equity firms.

(6) The award guidelines do not prevent an agency from funding SBIR/STTR projects from other (non-SBIR/STTR) agency funds. Non-SBIR/STTR funds used on SBIR/STTR efforts do not count toward the award guidelines set forth in (i)(1).

(j) *National Security Exemption.* The Act provides for exemptions related to the simplified standardized funding process "if national security or intelligence functions clearly would be jeopardized." This exemption should not be interpreted as a blanket exemption or prohibition of SBIR/STTR participation related to the acquisition of effort on national security or intelligence functions except as specifically defined under § 9(e)(2) of the Act, 15 U.S.C. 638(e)(2). Agency technology managers directing R/R&D projects under the SBIR and STTR programs, where the project subject matter may be affected by this exemption, must first make a determination on which, if any, of the standardized proceedings clearly place

national security and intelligence functions in jeopardy, and then proceed with an acceptable modified process to complete the SBIR/STTR action. SBA's SBIR/STTR program monitoring activities, except where prohibited by security considerations, must include a review of nonconforming SBIR/STTR actions justified under this public law provision.

(k) *Management of the STTR Project* [STTR only]. The SBC, and not its partnering Research Institution(s), is to provide satisfactory evidence that it will exercise management direction and control of the performance of the STTR Funding Agreement. Regardless of the proportion of the work or funding allocated to each of the performers under the Funding Agreement, the SBC is to be the primary party with overall responsibility for performance of the project. All agreements between the SBC and the Research Institution cooperating in the STTR Funding Agreement, or any business plans reflecting agreements and responsibilities between the parties during performance of STTR Phase I or Phase II Funding Agreement, or for the Commercialization of the resulting technology, should reflect the controlling position of the SBC.

#### **8. Terms of Agreement Under SBIR/STTR Awards**

(a) *Proprietary Information Contained in Proposals.* The standardized SBIR/STTR Program Solicitation shall include provisions requiring the confidential treatment of any proprietary information, unless disclosure is otherwise required by law. The solicitation will require that all proprietary information be identified clearly and marked with a prescribed legend. Agencies may elect to require SBCs to limit proprietary information to that essential to the proposal and to have such information submitted on a separate page or pages keyed to the text. The Government, except solely for proposal review purposes, shall not use or disclose, or authorize any other person or entity to use or disclose, all proprietary information, regardless of type, submitted in a contract proposal or grant application for a Funding Agreement under the SBIR/STTR programs.

(b) *Rights in Data Developed under an SBIR/STTR Funding Agreement.*

(1) *General.* The Act provides for retention by an SBC Awardee of the rights to Data generated by the concern in the performance of an SBIR/STTR award. These data rights provide an incentive for SBCs to participate in Federally-funded research projects and contribute to the ability of small

business Awardees to commercialize the technology developed under the program. The central purpose of SBIR/STTR Data Rights is to provide the Federal Government with the degree of access to an Awardee's SBIR/STTR Data needed to evaluate the work and effectively utilize the results and at the same time ensure that the Federal Government or other concerns cannot use SBIR/STTR Data in ways (e.g., for commercial purposes or to produce future technical procurement specifications) that would inappropriately diminish the rights or associated economic opportunities of the small business that developed the Data. The SBIR/STTR Data Rights provisions and definitions provided in this Policy Directive are designed to ensure that, for properly marked SBIR/STTR Data, during the SBIR/STTR Protection Period, the Federal Government provides effective protection of the Data that is comparable to and at least as strong as the protection the Federal Government gives to delivered proprietary Data that is developed exclusively at private expense.

(2) *Application of SBIR/STTR Data Rights.* SBIR/STTR Participating Agencies must ensure that Awardees of an SBIR/STTR Funding Agreement retain appropriate proprietary rights for all SBIR/STTR Data generated in the performance of the award. In general, this results in the Government receiving SBIR/STTR Data Rights in all SBIR/STTR Data during the SBIR/STTR Protection Period, except for certain types of Data that are not subject to such data rights restrictions due to the nature of the data (e.g., Form, Fit, and Function Data or OMIT Data). SBIR/STTR Data Rights apply to all SBIR/STTR awards, including subcontracts or subgrants to such awards, that fall within the statutory definition of Phase I, II, or III of the SBIR/STTR programs, as described in § 4 of this Policy Directive. The scope and extent of the SBIR/STTR Data Rights applicable to Federally-funded Phase III awards are identical to the SBIR/STTR Data Rights applicable to Phases I and II SBIR/STTR awards. SBIR/STTR Data Rights provide license rights to the Federal Government. SBIR/STTR Data Rights restrict the Federal Government's use and release of properly marked SBIR/STTR Data only during the SBIR/STTR Protection Period; after the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government Purposes, and is relieved of disclosure prohibitions related to such

Government Purposes, and assumes no liability for unauthorized use of these data by third parties. There is one exception to the rule that all Federal agencies receive Government Purpose rights in SBIR/STTR Data after the protection period. This exception is limited to the U.S. Department of Energy (DOE), whose statutory authorities, it has argued, mandates that it release and disclose all Government funded SBIR/STTR Data after the protection period. These authorities are the Atomic Energy Act of 1954, Public Law 83-703, 42 U.S.C. 2013(b); Energy Reorganization Act of 1974 (ERA), Public Law 93-438, 42 U.S.C. 5813(7); and the Department of Energy Organization Act of 1977 (DEOA), 42 U.S.C. 7112(5). Based on these authorities, DOE receives Unlimited Rights in SBIR/STTR Data upon expiration of the SBIR/STTR Protection Period, and this exception is limited to DOE. The Federal Government receives Unlimited Rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

(3) *SBIR/STTR Data Rights—Main Elements:*

(i) An SBC retains title and ownership of all SBIR/STTR Data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR Data that are not granted to the Government in accordance with this Policy Directive. These rights of the SBC do not expire.

(ii) The Government receives SBIR/STTR Data Rights during the SBIR/STTR Protection Period on all appropriately marked SBIR/STTR Data. These rights enable the Federal Government to use SBIR/STTR Data in limited ways within the Government, such as for project evaluation purposes, but are intended to prohibit uses and disclosures of the SBIR/STTR Data that may undermine the SBC's future Commercialization of the associated technology. The Government receives Unlimited Rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

(iii) After the SBIR/STTR Protection Period has expired, the Federal Government may use, and authorize others to use on its behalf, for Government Purposes, SBIR/STTR Data that was subject to SBIR/STTR Data Rights during the SBIR/STTR Protection Period. However, SBIR/STTR Data developed under awards issued by DOE are subject to Unlimited Rights after the SBIR/STTR Protection Period has expired.

(4) *SBIR/STTR Protection Period.* The SBIR/STTR Protection Period begins with award of an SBIR/STTR Funding

Agreement and ends twenty years, or longer at the discretion of the Participating Agency, from the date of award of an SBIR/STTR Funding Agreement (either Phase I, Phase II, or Federally-funded SBIR/STTR Phase III) unless subsequent to the award, the agency and the SBC negotiate for some other protection period for the SBIR/STTR Data.

(5) *Marking Requirements, and Requirements for Omitted or Incorrect Markings.* To receive the protections accorded to SBIR/STTR Data pursuant to SBIR/STTR Data Rights, any SBIR/STTR Data that is delivered must be marked with the appropriate SBIR/STTR Data Rights legend or notice, in accordance with agency procedures. The Government assumes no liability for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR Data without markings. If SBIR/STTR Data is delivered without the required legend or notice, the SBIR/STTR Awardee may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR Data legend or notice, as applicable, placed on qualifying Data. If SBIR/STTR Data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the Awardee's expense of such incorrect or nonconforming notice(s).

(6) *Negotiated Rights.*

(i) *Specially Negotiated Licenses Authorized Only After Award.* An agency must not, in any way, make issuance of an SBIR/STTR award conditional upon the Awardee negotiating or consenting to negotiate a specially negotiated license or other agreement regarding SBIR/STTR Data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.

(ii) Following issuance of an SBIR/STTR award, the Awardee may enter into a written agreement with the awarding agency to modify the license rights that would otherwise be granted to the agency during the SBIR/STTR Protection Period. However, any such agreement must be entered into voluntarily and by mutual agreement of the SBIR/STTR Awardee and agency, and not a condition for additional work under the Funding Agreement or the exercise of options. Such a bilateral data rights agreement must be entered into only after the subject SBIR/STTR award (which award must include an appropriate SBIR/STTR Data Rights clause) has been signed. Any such specially negotiated license must be in

writing under a separate agreement after the SBIR/STTR Funding Agreement is signed. A decision by the Awardee to relinquish, transfer, or modify in any way its rights in SBIR/STTR Data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR Data Rights shall have no effect on the provision of SBIR/STTR Data Rights in a resulting Phase I, Phase II, or Phase III award.

(7) *SBIR/STTR Data Rights Clause.* To ensure that SBIR/STTR Awardees receive the applicable data rights, all SBIR and STTR solicitations and resulting Funding Agreements must fully implement all of the policies, procedures, and requirements set forth in this Policy Directive in appropriate provisions and clauses incorporated into the SBIR/STTR solicitations and awards. Paragraph (5)(d)(3) of Appendix I: Instructions for Preparation of SBIR/STTR Program Solicitations provides a sample SBIR/STTR Data Rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.

(c) *Non-disclosure Agreement for Releases Outside the Government.* In accordance with the Government's SBIR/STTR Data Rights, the Government must enter into an appropriate non-disclosure agreement (NDA) with any non-Governmental entity that is authorized to receive SBIR/STTR Data (that is subject to SBIR/STTR Data Rights) during the SBIR/STTR Protection Period, except as otherwise permitted by the Awardee asserting the SBIR/STTR Data Rights. The NDA must contain terms and conditions to ensure that the non-governmental entity:

(1) Understands, acknowledges, and agrees that its use, modification, reproduction, release, display, disclosure, and distribution of the SBIR/STTR Data is permitted only for the specific activities authorized by the NDA (which must be authorized by SBIR/STTR Data Rights, or otherwise authorized by the SBIR/STTR Awardee);

(2) Is prohibited from further using, modifying, reproducing, releasing, displaying, disclosing, or distributing the Data unless it receives the written permission of the Federal Government (when authorized by the SBIR/STTR Awardee) or the written permission of the SBIR/STTR Awardee;

(3) Agrees to destroy (or return to the Federal Government at the request of the Government), all SBIR/STTR Data, and all copies in its possession, at or before the time specified in the agreement, and to notify the procuring agency that all copies have been destroyed (or returned as requested by the Government);

(4) Is prohibited from using the data for a commercial purpose unless it receives the written permission of the Federal Government (when authorized by the SBIR/STTR Awardee) or the written permission of the SBIR/STTR Awardee itself; and

(5) Ensures that its employees, subcontractors, and other entities that are authorized to receive SBIR/STTR Data are bound by use and non-disclosure restrictions consistent with the NDA prior to being provided access to such SBIR/STTR Data.

(d) *[STTR only] Allocation of Intellectual Property Rights in STTR Award.*

(1) An SBC, before receiving an STTR award, must negotiate a written agreement between the SBC and the partnering Research Institution, allocating Intellectual Property rights and rights, if any, to carry out follow-on research, development, or Commercialization. The SBC must submit this agreement to the awarding agency with the proposal. The SBC must certify in all proposals that the agreement is satisfactory to the SBC.

(2) The awarding agency may accept an existing agreement between the two parties if the SBC certifies its satisfaction with the agreement, and such agreement does not conflict with the interests of the Government. SBA will provide a model agreement to be adopted by the agencies and used as guidance by the SBC in the development of an agreement with the Research Institution. The model agreement will direct the parties to, at a minimum:

(i) State specifically the degree of responsibility, and ownership of any product, process, or other invention or Innovation resulting from the cooperative research. The degree of responsibility shall include responsibility for expenses and liability, and the degree of ownership shall also include the specific rights to revenues and profits.

(ii) State which party may obtain United States or foreign patents or otherwise protect any inventions resulting from the cooperative research.

(iii) State which party has the right to any continuation of research, including non-STTR follow-on awards.

(3) The Government will not normally be a party to any agreement between the SBC and the Research Institution. Nothing in the agreement is to conflict with any provisions setting forth the respective rights of the United States and the SBC with respect to Intellectual Property rights and with respect to any right to carry out follow-on research.

(e) *Title Transfer of Agency-Provided Property.* Under the Act, the Federal Government may transfer title to property provided by the SBIR/STTR Participating Agency to the Awardee or acquired by the Awardee for the purpose of fulfilling the contract where such transfer would be more cost effective than recovery of the property.

(f) *Continued Use of Government Equipment.* Agencies must allow an SBIR/STTR Awardee participating in an SBIR/STTR Phase III award continued use, as a directed bailment, of any property transferred by the agency to the Phase II Awardee or acquired by the Awardee for the purpose of fulfilling the contract. The Phase II Awardee may use the property for a period of not less than 2 years, beginning on the initial date of the concern's participation in the third phase of the SBIR/STTR program.

(g) *Grant Authority.* The Act does not, in and of itself, convey grant authority. Each agency must secure grant authority in accordance with its normal procedures.

(h) *Conflicts of Interest.* SBA cautions Participating Agencies that awards made to SBCs owned by or employing current or previous Federal Government employees may create conflicts of interest in violation of FAR part 3 and the Ethics in Government Act of 1978, as amended. Each Participating Agency should refer to the standards of conduct review procedures currently in effect for its agency to ensure that such conflicts of interest do not arise.

(i) *American-Made Equipment and Products.* Congress intends that the Awardee of a Funding Agreement under the SBIR/STTR program should, when purchasing any equipment or a product with funds provided through the Funding Agreement, purchase only American-made equipment and products, to the extent possible, in keeping with the overall purposes of this program. Each SBIR/STTR Agency must provide to each Awardee a notice of this requirement.

(j) *Certifications After Award and During Funding Agreement Life Cycle.*

(1) A Phase I Funding Agreement must state that the Awardee shall submit a new certification as to whether it is in compliance with specific SBIR/STTR program requirements at the time of final payment or disbursement.

(2) A Phase II Funding Agreement must state that the Awardee shall submit a new certification as to whether it is in compliance with specific SBIR/STTR program requirements prior to receiving more than 50% of the total award amount and prior to final payment or disbursement.

(3) Agencies may also require additional certifications at other points in time during the life cycle of the Funding Agreement, such as at the time of each payment or disbursement.

(k) *Updating www.SBIR.gov.* Agencies must require each Phase II Awardee to update the Commercialization information on the award through the company's account on *www.SBIR.gov* upon completion of the last deliverable under the Funding Agreement. In addition, the Awardee is requested to voluntarily update the Commercialization information on that award annually thereafter for a minimum period of 5 years.

(l) *Prototypes.* Participating Agencies must handle all Prototypes developed under an SBIR/STTR award with caution during the SBIR/STTR Protection Period to prevent any use or disclosure of these items that has the potential to reveal the innovative aspects of the technology in ways that may harm the Awardee's ability to commercialize the technology. In particular, reverse engineering of Prototypes may reveal, to a Government or non-Government entity, the SBIR/STTR Data that is applied or embodied in the item. While a Prototype may not itself be considered SBIR/STTR Data because it is not "recorded information," SBA cautions agencies that it is a violation of the purpose and intent of the Act to release or use a Prototype during the SBIR/STTR Protection Period in a way that harms the Awardee's ability to take advantage of the economic opportunities of its SBIR/STTR Data. SBA notes that the Defense Federal Acquisition Regulations Supplement (DFARS) Restricted Rights license granted to the Government for Computer Software prohibits non-Governmental entities from reverse-engineering, disassembly, or decompiling Computer Software (including computer software embedded within hardware), except in extremely limited circumstances.

## 9. Responsibilities of SBIR/STTR Agencies and Departments

(a) *General Responsibilities.* Each agency participating in the SBIR/STTR program must:

(1) Unilaterally determine the categories of projects to be included in its SBIR/STTR program, giving

consideration to maintaining a portfolio balance between exploratory projects of high technological risk and those with greater likelihood of success. Further, to the extent permitted by the law, and in a manner consistent with the mission of that agency and the purpose of the SBIR/STTR program, each Federal agency must:

(i) Give priority in the SBIR/STTR program to manufacturing-related research and development in accordance with Executive Order 13329. In addition, agencies must develop an Action Plan for implementing Executive Order 13329, which identifies activities used to give priority in the SBIR/STTR program to manufacturing-related research and development. These activities should include the provision of information on the Executive Order on the agency's SBIR/STTR program website.

(ii) give priority to SBCs that participate in or conduct energy efficiency or renewable energy system research and development projects.

(iii) give consideration to topics that further one or more critical technologies as identified by the National Critical Technologies panel (or its successor) in reports required under 42 U.S.C. 6683, or the Secretary of Defense in accordance with 10 U.S.C. 2522.

(2) Release SBIR/STTR solicitations in accordance with the SBA master schedule.

(3) Unilaterally receive and evaluate proposals resulting from Program Solicitations, select Awardees, issue Funding Agreements, and inform each Awardee under such agreement, to the extent possible, of the expenses of the Awardee that will be allowable under the Funding Agreement.

(4) Require a succinct Commercialization plan with each proposal submitted for a Phase II award.

(5) Collect and maintain information from Applicants and Awardees and provide it to SBA to develop and maintain the database, as identified in § 11(c) of this Policy Directive.

(6) Administer its own SBIR/STTR Funding Agreements or delegate such administration to another agency. Such administrative services include the use of assisted acquisition service providers under the terms and conditions of a properly executed Interagency Agreement.

(7) Include provisions in each SBIR/STTR Funding Agreement setting forth the respective rights of the United States and the Awardee with respect to Intellectual Property rights and with respect to any right to carry out follow-on research.

(8) Ensure that the rights in Data developed under each Federally-funded SBIR/STTR Phase I, Phase II, and Phase III award are protected properly.

(9) Make payments to Awardees of SBIR/STTR Funding Agreements on the basis of progress toward or completion of the Funding Agreement requirements and in all cases make payment to Awardees under such agreements in full, subject to audit, on or before the last day of the 12-month period beginning on the date of completion of such requirements.

(10) Provide an annual report on the SBIR/STTR program to SBA, as well as other information concerning the SBIR/STTR program. See § 10 of this Policy Directive for further information on the agency's reporting requirements, including the frequency for specific reporting requirements.

(11) Include in its annual performance plan required by 31 U.S.C. 1115(a) and (b) a section on its SBIR/STTR program, and submit such section to the Senate Committee on Small Business and Entrepreneurship and to the House Committees on Science, Space and Technology and Small Business.

(12) Establish the agency's benchmarks for progress towards Commercialization and include the information necessary to implement the benchmarks in each solicitation. See § 6(a)(7) of the directive for further information.

(b) *Discretionary Technical and Business Assistance to SBIR/STTR Awardees.*

(1) Agencies may enter into agreements with 1 or more vendors to provide technical and business assistance to SBIR/STTR Awardees, which may include access to a network of scientists and engineers engaged in a wide range of technologies, assistance with product sales, intellectual property protections, market research, market validation, and development of regulatory plans and manufacturing plans, or access to technical and business literature available through on-line databases. For a term not to exceed 5 years, each agency may select 1 or more vendors from which small business concerns may obtain assistance. Such selection must be based on competitive and merit-based criteria.

(i) The purpose of this technical and business assistance is to assist SBIR/STTR Awardees in:

(A) making better technical decisions on SBIR/STTR projects;

(B) solving technical problems that arise during SBIR/STTR projects;

(C) minimizing technical risks associated with SBIR/STTR projects; and

(D) commercializing the SBIR/STTR product or process, including intellectual property protections.

(ii) An agency may not enter into a contract with the vendor if the contract amount provided for technical assistance is based upon the total number of Phase I or Phase II awards, but may enter into a contract with the vendor based upon the total amount of awards for which assistance is provided.

(2) Each agency may provide up to \$6,500 of SBIR/STTR funds for the technical and business assistance described above in (b)(1) per year for each Phase I award, which shall be in addition to the amount of the award. Each agency may provide up to \$50,000 of SBIR/STTR funds for technical and business assistance described above in (b)(1) per project for Phase II awards. The amount of technical and business assistance for Phase II awards, as determined appropriate by the head of the Federal agency, may be included as part of the recipient's award or be in addition to the amount of the recipient's award. The agency may not use SBIR/STTR funds for technical and business assistance unless a vendor provides the services to the SBIR/STTR Awardee.

(3) A small business concern may, by contract or otherwise, select 1 or more vendors to assist the small business concern in meeting the goals listed in paragraph (1). An SBIR/STTR Applicant may acquire the technical assistance services set forth in (b)(1)(i) above itself rather than through a vendor selected by the Federal Agency. The Applicant must request the authority to select its own technical and business assistance provider from the Federal Agency and demonstrate in its SBIR/STTR application that the individual or entity selected can provide the specific technical and business services needed. If the Awardee demonstrates this requirement sufficiently, the agency shall permit the Awardee to acquire such technical and business assistance itself, in an amount up to \$6,500 per year for Phase I awards and up to \$50,000 per award for Phase II awards, as an allowable cost of the SBIR/STTR award. The amount of technical and business assistance for Phase I awards shall be in addition to the amount of the award. Phase II awards, as determined appropriate by the head of the Federal agency, may be included as part of the recipient's award or be in addition to the amount of the recipient's award. The applicant may also seek business-related services aimed at improving the commercialization success of a small business concern from an entity, such as a public or private organization or an agency of or other entity established or

funded by a State that facilitates or accelerates the commercialization of technologies or assists in the creation and growth of private enterprises that are commercializing technology.

(4) SBA must establish a limit on the value of business and technical assistance services received or purchased by SBCs awarded multiple Phase II awards in a fiscal year. SBA will seek public comment to gather input on the appropriate limit and will provide guidance on [www.SBIR.gov](http://www.SBIR.gov).

(5) A small business concern that receives technical or business assistance from a vendor during a fiscal year shall submit to the Federal agency contracting with the vendor a description of the technical or business assistance provided and the benefits and results of the technical or business assistance provided. The information required shall be collected by a Federal agency as part of a report required to be submitted by small business concerns engaged in SBIR or STTR projects of the Federal agency for which the requirement was in effect on August 13, 2018.

(6) Not later than the end of fiscal year 2019, the Administrator of the Small Business Administration shall—

(A) Conduct a survey of vendors providing technical or business assistance under section 9(q) of the Small Business Act (15 U.S.C. 638(q)), and small business concerns receiving the technical or business assistance; and

(B) Submit to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business of the House of Representatives a report reviewing the efficacy of the provision of the technical or business assistance.

(c) *Timelines for Awards.* Agencies must publish the information relating to timelines for awards of Phase I and Phase II Funding Agreements and performance start dates of the Funding Agreements that are reported to SBA in the agency's Annual Report (see § 10(a) of this Policy Directive). SBA will also publish this information on [www.SBIR.gov](http://www.SBIR.gov).

(d) *Interagency actions.*

(1) *Joint funding.* An SBIR/STTR project may be financed by more than one Federal Agency. Joint funding is not required but can be an effective arrangement for some projects.

(2) *Phase II awards.* An SBIR/STTR Phase II award may be issued by a Federal Agency other than the one that made the Phase I award. Prior to award, the head of the Federal Agency for the Phase I and Phase II awards, or designee, must issue a written determination that the topics of the

awards are the same. Both agencies must submit the report to SBA.

(3) *Participation by WOSBs and SDBs in the SBIR/STTR Program.* In order to meet statutory requirements for greater inclusion, SBA and the Participating Agencies must conduct outreach efforts to find and place innovative WOSBs and SDBs in the SBIR/STTR program. These SBCs will be required to compete for SBIR/STTR awards on the same basis as all other SBCs. However, SBIR/STTR Agencies are encouraged to work independently and cooperatively with SBA to develop methods to encourage qualified WOSBs and SDBs to participate in the SBIR/STTR program.

(4) *Interagency Assisted Acquisitions.* A Participating Agency may obtain assistance, as needed to meet its mission, by entering into a properly executed Interagency Agreement with another Federal Agency for the provision of acquisition services to award and administer funding agreements.

(e) *Limitation on use of funds.*

(1) Each SBIR/STTR Agency must expend the required minimum percent of its extramural budget on awards to SBCs. Agencies may not make available for the purposes of meeting the minimum percent an amount of its extramural budget for basic research that exceeds the minimum percent required for that year. Funding Agreements with SBCs for R/R&D that result from competitive or single source selections other than an SBIR/STTR program must not be considered to meet any portion of the required minimum percent.

(2) An agency must not use any of its SBIR/STTR budget for the purpose of funding administrative costs of the program, including costs associated with program operations, employee salaries, and other associated expenses, unless the exception in paragraph (3) below or § 12(b)(4)(ii) of this Policy Directive applies.

(3) *Funding of Administrative, Oversight, and Contract Processing Costs.* Upon establishment by SBA of the agency-specific performance criteria, SBA shall allow an SBIR Participating Agency to use no more than 3% of its SBIR budget for one or more specific activities, which may be prioritized by the Federal SBIR/STTR Interagency Policy Committee. The purpose of this program is to assist with the substantial expansion in commercialization activities, prevention of fraud/waste/abuse, expansion of reporting requirements by agencies and other agency activities required for the SBIR program. Funding under this program is not intended to and must not replace

current agency administrative funding in support of SBIR/STTR activities. Rather, funding under this program is intended to supplement such funds. The authority for this program shall terminate on September 30, 2022, unless otherwise extended.

(i) A Federal Agency may use this money to fund the following specific activities:

(A) SBIR and STTR program administration, which includes:

(I) Internal oversight and quality control, such as verification of reports and invoices and cost reviews, and waste/fraud/abuse prevention (including targeted reviews of SBIR/STTR Awardees that an agency determines are at risk for waste/fraud/abuse);

(II) carrying out any activities associated with the participation by small businesses that are majority-owned by multiple venture capital operating companies, hedge funds or private equity firms;

(III) contract processing costs relating to the SBIR or STTR program of that agency, which includes supplementing the current workforce to assist solely with SBIR or STTR Funding Agreements;

(IV) funding of additional personnel to work solely on the SBIR/STTR program of that agency, which includes assistance with application reviews; and

(V) funding for simplified and standardized program proposal, selection, contracting, compliance, and audit procedures for the SBIR/STTR program, including the reduction of paperwork and data collection.

(VI) funding for improvements that increase commonality across data systems, reduce redundancy, and improve data oversight and accuracy.

(B) SBIR or STTR program-related outreach and related technical assistance initiatives not in effect prior to commencement of this pilot, except significant expansion or improvement of these initiatives, including:

(I) Technical assistance site visits;

(II) personnel interviews;

(III) national conferences;

(C) Commercialization initiatives not in effect prior to commencement of this pilot, except significant expansion or improvement of these initiatives.

(D) For DoD and the military departments, carrying out the Commercialization Readiness Program set forth in § 12(b) of this Policy Directive, with emphasis on supporting new initiatives that address barriers in bringing SBIR/STTR technologies to the marketplace, including Intellectual Property issues, sales cycle access

issues, accelerated technology development issues, and other issues.

(ii) Agencies must use this money to attempt to increase participation by SDBs and WOSBs in the SBIR/STTR program, and small businesses in states with a historically low level of SBIR/STTR awards. The agency may submit a written request to SBA to waive this requirement. The request must explain why the waiver is necessary, demonstrate a sufficient need for the waiver, and explain that the outreach objectives of the agency are being met and that there has been increased participation by small businesses in states with a historically low level of SBIR/STTR awards.

(iii) SBA will establish performance criteria each fiscal year by which use of these funds will be evaluated for that fiscal year. The performance criteria will be metrics that measure the performance areas required by statute against the goals set by the agencies in their work plans. The performance criteria will be based upon the work plans submitted by each agency for a given fiscal year and will be agency-specific. SBA will work with the SBIR/STTR Agencies in creating a simplified template for agencies to use when making their work plans.

(iv) Each agency must submit its work plan to SBA at least 30 calendar days prior to the start of each fiscal year for which the pilot program is in operation. Agency work plans must include the following: A prioritized list of initiatives to be supported; the estimated percentage of administrative funds to be allocated to each initiative or the estimated amounts to be spent on each initiative; milestones for implementing the initiatives; the expected results to be achieved; and the assessment metrics for each initiative. The work plan must identify initiatives that are above and beyond current practice and which enhance the agency's SBIR/STTR program.

(v) SBA will evaluate the work plan and provide initial comments within 15 calendar days of receipt of the plan. SBA's objective in evaluating the work plan is to ensure that, overall, it provides for improvements to the SBIR/STTR program of that particular agency. If SBA does not provide initial comments within 30 calendar days of receipt of the plan, the work plan is deemed to be approved. If SBA does submit initial comments within 30 calendar days, agencies must amend or supplement their work plan and resubmit to SBA. Once SBA establishes the agency-specific performance criteria to measure the benefits of the use of these funds under the work plan, the

agency may begin using the SBIR funds for the purposes set forth in the work plan. Agencies can adjust their work plans and spending throughout the fiscal year as needed, but must notify SBA of material changes in the plan.

(vi) Agencies must coordinate any activities in the work plan that relate to fraud, waste, and abuse prevention, targeted reviews of Awardees, and implementation of oversight control and quality control measures (including verification of reports and invoices and cost reviews) with the agency's Office of Inspector General (OIG). If the agency allocates more than \$50,000,000 to its SBIR program for a fiscal year, the agency may share this funding with its OIG when the OIG performs the activities.

(vii) Agencies shall report to the Administrator of the SBA on use of funds under this authority as part of the SBIR/STTR Annual Report. *See* § 10 generally and § 10(i) of this Policy Directive.

(4) An agency must not issue an SBIR/STTR Funding Agreement that includes a provision for subcontracting any portion of that agreement back to the issuing agency, to any other Federal Government agency, or to other units of the Federal Government, except as provided in paragraph (e)(5) below. SBA may issue a case-by-case waiver to this provision after review of an agency's written justification that includes the following information:

(i) An explanation of why the SBIR/STTR research project requires the use of the Federal facility or personnel, including data that verifies the absence of non-Federal facilities or personnel capable of supporting the research effort.

(ii) Why the Federal Agency will not and cannot fund the use of the Federal facility or personnel for the SBIR/STTR project with non-SBIR/STTR money.

(iii) The concurrence of the SBC's chief business official to use the Federal facility or personnel.

(5) An agency may issue an SBIR/STTR Funding Agreement to an SBC that intends to enter into an agreement with a Federal Laboratory to perform portions of the award or has entered into a cooperative research and development agreement (*see* 15 U.S.C. 3710a(d)) with a Federal Laboratory, only if there is compliance with the following.

(i) The agency may not require that the SBC enter into an agreement with any Federal Laboratory to perform any portion of an SBIR/STTR award, as a condition for an SBIR/STTR award.

(ii) The agency may not issue an SBIR/STTR award or approve an

agreement between an SBIR/STTR Awardee and a Federal Laboratory if the SBC will not meet the minimum performance of work requirements set forth in § 6(a)(4) of this Policy Directive.

(iii) The agency may not issue an SBIR/STTR award or approve an agreement between an SBIR/STTR Awardee and a Federal Laboratory that violates any SBIR/STTR requirement set forth in statute or this Policy Directive, including any SBIR/STTR Data Rights protections.

(iv) The Federal Agency and Federal Laboratory may not require any SBIR/STTR Awardee that has an agreement with the Federal Laboratory to perform portions of the activities under the SBIR/STTR award to provide advance payment to the Federal Laboratory in an amount greater than the amount necessary to pay for 30 days of such activities.

(6) No agency, at its own discretion, may unilaterally cease participation in the SBIR/STTR program. R/R&D agency budgets may cause fluctuations and trends that must be reviewed in light of SBIR/STTR program purposes. An agency may be considered by SBA for a phased withdrawal from participation in the SBIR/STTR program over a period of time sufficient in duration to minimize any adverse impact on SBCs. However, the SBA decision concerning such a withdrawal will be made on a case-by-case basis and will depend on significant changes to extramural R/R&D 3-year forecasts as found in the annual Budget of the United States Government and NSF National Center for Science Engineering Statistics (NCSES) breakdowns of total R/R&D obligations as published in the Survey of Federal Funds for Research and Development. Any withdrawal of an SBIR/STTR agency from the SBIR/STTR program will be accomplished in a standardized and orderly manner in compliance with these statutorily mandated procedures.

(7) Any Federal agency which has an extramural R/R&D budget in excess of \$100,000,000 based on 3-year forecasts as found in the annual Budget of the United States Government and NSF NCSES Survey of Federal Funds for Research and Development should start participation in the SBIR program. Any Federal agency which has an extramural R/R&D budget in excess of \$1,000,000,000 based on 3-year forecasts as found in the annual Budget of the United States Government and NSF NCSES Survey of Federal Funds for Research and Development should start participation in the STTR program. SBA will monitor the NCSES Survey of Federal Funds for Research and Development and notify a Federal

agency if it appears to be required to begin participation in the SBIR and/or STTR program, but it is the responsibility of Federal agencies to implement the institution of its agency's SBIR and/or STTR program. Federal agencies not otherwise required to participate in the SBIR/STTR program may participate on a voluntary basis. Federal agencies seeking to participate in the SBIR/STTR program must first submit their written requests to SBA. Voluntary participation requires the written approval of SBA.

(f) *Preventing Fraud, Waste, and Abuse.*

(1) Agencies shall evaluate risks of fraud, waste, and abuse in each application, monitor and administer SBIR/STTR awards, and create and implement policies and procedures to prevent fraud, waste and abuse in the SBIR/STTR program. To capitalize on OIG expertise in this area, agencies must consult with their OIG when creating such policies and procedures. Fraud includes any false representation about a material fact or any intentional deception designed to deprive the United States unlawfully of something of value or to secure from the United States a benefit, privilege, allowance, or consideration to which an individual or business is not entitled. Waste includes extravagant, careless, or needless expenditure of Government funds, or the consumption of Government property, that results from deficient practices, systems, controls, or decisions. Abuse includes any intentional or improper use of Government resources, such as misuse of rank, position, or authority or resources. Examples of fraud, waste, and abuse relating to the SBIR/STTR program include, but are not limited to:

- (i) Misrepresentations or material, factual omissions to obtain, or otherwise receive funding under, an SBIR/STTR award;
- (ii) misrepresentations of the use of funds expended, work done, results achieved, or compliance with program requirements under an SBIR/STTR award;
- (iii) misuse or conversion of SBIR/STTR award funds, including any use of award funds while not in full compliance with SBIR/STTR program requirements, or failure to pay taxes due on misused or converted SBIR/STTR award funds;
- (iv) fabrication, falsification, or plagiarism in applying for, carrying out, or reporting results from an SBIR/STTR award;
- (v) failure to comply with applicable federal costs principles governing an award;

(vi) extravagant, careless, or needless spending;

(vii) self-dealing, such as making a sub-award to an entity in which the PI has a financial interest;

(viii) acceptance by agency personnel of bribes or gifts in exchange for grant or contract awards or other conflicts of interest that prevent the Government from getting the best value; and

(ix) lack of monitoring, or follow-up if questions arise, by agency personnel to ensure that Awardee meets all required eligibility requirements, provides all required certifications, performs in accordance with the terms and conditions of the award, and performs all work proposed in the application.

(2) At a minimum, agencies must:

(i) Require certifications from the SBIR/STTR Awardee at the time of award, as well as after award and during the Funding Agreement life cycle (*see* § 8(i) and Appendix I for more information);

(ii) Include on their respective SBIR/STTR web page and in each solicitation, information explaining how an individual can report fraud, waste and abuse as provided by the agency's OIG (*e.g.*, include the fraud hotline number or web-based reporting method for the agency's OIG);

(iii) Designate at least one individual in the agency to, at a minimum, serve as the liaison for the SBIR/STTR program, the OIG and the agency's Suspension and Debarment Official (SDO) and ensure that inquiries regarding fraud, waste and abuse are referred to the OIG and, if applicable, the SDO.

(iv) Include on their respective SBIR/STTR web page information concerning successful prosecutions of fraud, waste and abuse in the SBIR or STTR programs.

(v) Establish a written policy requiring all personnel involved with the SBIR/STTR program to notify the OIG if anyone suspects fraud, waste, and/or abuse and ensure the policy is communicated to all SBIR/STTR personnel.

(vi) Create or ensure there is an adequate system to enforce accountability (through suspension and debarment, fraud referrals or other efforts to deter wrongdoing and promote integrity) by developing separate standardized templates for a referral made to the OIG for fraud, waste and abuse or the SDO for other matters, and a process for tracking such referrals.

(vii) Ensure compliance with the eligibility requirements of the program and the terms of the SBIR/STTR Funding Agreement.

(viii) Work with the agency's OIG with regard to its efforts to establish fraud detection indicators, coordinate the sharing of information between Federal Agencies, and improve education and training to SBIR/STTR program officials, Applicants and Awardees;

(ix) Develop policies and procedures to avoid funding Essentially Equivalent Work already funded by the same or another agency, which could include: Searching *www.SBIR.gov* prior to award for the Applicant (if a Joint Venture, search for each party to the Joint Venture), Key Individuals of the Applicant, and similar abstracts; using plagiarism or other software; checking the SBC's certification prior to award and funding and documenting the Funding Agreement file that such certification evidenced the SBC has not already received funding for Essentially Equivalent Work; reviewing other agencies' policies and procedures for best practices; and reviewing other R&D programs for policies and procedures and best practices related to this issue; and

(x) Consider enhanced reporting requirements during the Funding Agreement.

(g) *Interagency Policy Committee.* The Director of the Office of Science and Technology Policy (OSTP) will establish an Interagency SBIR/STTR Policy Committee, which will include representatives from Federal Agencies with an SBIR or an STTR program and SBA. The Interagency SBIR/STTR Policy Committee shall review the following issues (but may review additional issues) and make policy recommendations on ways to improve program effectiveness and efficiency:

(1) The *www.SBIR.gov* databases described in section 9(k) of the Act (15 U.S.C. 638(k));

(2) Federal Agency flexibility in establishing Phase I and II award sizes, including appropriate criteria for exercising such flexibility;

(3) Commercialization assistance best practices of Federal Agencies with significant potential to be employed by other agencies and the appropriate steps to achieve that leverage, as well as proposals for new initiatives to address funding gaps that business concerns face after Phase II but before Commercialization.

(4) The need for a standard evaluation framework to enable systematic assessment of SBIR and STTR, including through improved tracking of awards and outcomes and development of performance measures for the SBIR program and STTR program of each Federal Agency.

(5) Identification and sharing of best practices and the leveraging of resources in support of increasing the participation of small businesses underrepresented in the SBIR and STTR programs, including outreach and technical assistance activities for Applicants, Awardees, and others.

(h) *National Academy of Science Report.* The National Academy of Sciences (NAS) will conduct a study and issue reports on the SBIR and STTR programs.

(1) Prior to and during the period of study, and to ensure that the concerns of small business are appropriately considered, NAS shall consult with and consider the views of SBA's Office of Investment and Innovation and the Office of Advocacy and other interested parties, including entities, organizations, and individuals actively engaged in enhancing or developing the technological capabilities of SBCs.

(2) The head of each agency with a budget of more than \$50,000,000 for its SBIR program for fiscal year 1999 shall, in consultation with SBA, and not later than 6 months after December 31, 2011, cooperatively enter into an agreement with NAS regarding the content and performance of the study. SBA and the agencies will work with the Interagency Policy Committee in determining the parameters of the study, including the specific areas of focus and priorities for the broad topics required by statute. The agreement with NAS must set forth these parameters, specific areas of focus and priorities, and comprehensively address the scope and content of the work to be performed. This agreement must also require the NAS to ensure there is participation by and consultation with, the small business community, the SBA, and other interested parties as described in paragraph (h)(1).

(3) NAS shall transmit to SBA, heads of agencies entering into an agreement

under this section, the Committee on Science, Space and Technology, the Committee on Small Business of the House of Representatives, and to the Committee on Small Business of the Senate a copy of the report, which includes the results and recommendations, not later than 4 years after December 31, 2011, and every subsequent four years.

**10. Reporting Requirements—for Participating Agencies, Applicants, and Awardees**

(a) *General.* The Act requires agencies to collect meaningful information from SBCs and ensure that reporting requirements are streamlined to minimize the burden on small businesses.

(1) SBA is required to collect data from Participating Agencies and report to the Congress information regarding applications by and awards to SBCs by each Federal Agency participating in the SBIR/STTR program. Participating Agencies report data using standardized templates that are provided, maintained, and updated by SBA on *www.SBIR.gov*.

(2) The Act requires a “simplified, standardized and timely annual report” from each Federal Agency participating in the SBIR/STTR program (see § 3 of the Policy Directive for the definition of Federal Agency), which is submitted to SBA. In addition, agencies are required to report certain items periodically throughout the year to SBA. Agencies may identify certain information, such as award data information, by the various components of each agency. SBA collects agency reports through the *www.SBIR.gov* portal. If the *www.SBIR.gov* databases are unavailable, then the report must be emailed to *technology@sba.gov*.

(3) To meet these requirements, the SBIR/STTR program has the following key principles:

(i) Make updating data available electronically;

(ii) Centralize and share certain data through secure interfaces to which only authorized Government personnel have access;

(iii) Have small business enter the data only once, if possible; and

(iv) Provide standardized procedures.

(b) *Summary of SBIR/STTR Databases.*

(1) The Act requires that SBA coordinate the implementation of electronic databases at the SBIR/STTR Agencies, including the technical ability of the agencies to share the data. In addition, the Act requires the reporting of various data elements, which are clustered together in the following subsections:

(i) Solicitations Database (to include the Master Schedule);

(ii) *www.SBIR.gov*, which includes the following databases:

- (A) Company Registry Database;
- (B) Application Information Database;
- (C) Award Information Database;
- (D) Commercialization Database;
- (E) Annual Report Database; and
- (F) Other Reporting Requirements Database.

(2) The subsections below describe the data reporting requirements, including reporting mechanisms, the frequency of data collection and reporting, and whether this information is shared publicly or is protected and only available to authorized personnel. The table below summarizes the data collection requirements for each database; however, there may be some divergences at the individual data field level. Refer to Appendix II (as posted on *www.SBIR.gov*) for the detailed reporting requirements at the data field level. SBA notes that in fiscal year 2012, SBA began a phased implementation of this data collection.

Database	Reporting mechanism	Collection/reporting frequency	Public/government
Solicitations .....	Agency XML or manual upload to <i>http://www.SBIR.gov</i> .	Within 5 business days of solicitation open date.	Public.
Company Registry .....	SBC reports data to <i>www.SBIR.gov</i> ; Agency receives .pdf from company.	Register or reconfirm at time of application.	Government only.
Application Information .....	Agency provides XML or manual upload to <i>www.SBIR.gov</i> .	Quarterly .....	Government only.
Award Information .....	Agency provides XML or manual upload to <i>www.SBIR.gov</i> .	Quarterly .....	Public.
Commercialization .....	Agencies + companies report to <i>www.SBIR.gov</i> .	Agencies update in real time; SBC updates prior to subsequent award application and voluntarily thereafter.	Government only.

Database	Reporting mechanism	Collection/reporting frequency	Public/government
Annual Report .....	Agency XML or manual upload to <a href="http://www.SBIR.gov">www.SBIR.gov</a> .	Annually .....	Government only. Summary SBA Annual Report based on Agency-submitted Annual Report data is Public.
Other Reports .....	As set forth in the directive .....	As set forth in the directive.	Public.

(3) SBIR/STTR Awardees will have user names and passwords assigned in order to access their respective awards information in the system. Award and Commercialization data maintained in the database can be changed only by the Awardee, SBA, or the awarding SBIR/STTR Participating Agency.

(c) *Master Schedule and the Solicitations Database.*

(1) SBA posts an electronic Master Schedule of release dates of Program Solicitations with links to internet websites of agency solicitations on [www.SBIR.gov](http://www.SBIR.gov).

(i) On or before August 1, each agency representative must notify SBA in writing or by email of its proposed Program Solicitation release and proposal due dates for the next fiscal year. SBA and the agency representatives will coordinate the resolution of any conflicting agency solicitation dates by the second week of August. In all cases, SBA will make final decisions. Agencies must notify SBA in writing of any subsequent changes in the solicitation release and close dates.

(ii) For those agencies that use both general topic and more specific subtopic designations in their SBIR/STTR solicitations, the topic data should accurately describe the research solicited.

(iii) Agencies must post on their internet websites the following information regarding each Program Solicitation:

(A) List of topics upon which R/R&D proposals will be sought;

(B) agency address, phone number, or email address from which SBIR/STTR Program Solicitations can be requested or obtained, especially through electronic means;

(C) names, addresses, and phone numbers of agency contact points where SBIR/STTR-related inquiries may be directed;

(D) release date(s) of Program Solicitation(s);

(E) closing date(s) for receipt of proposals; and

(F) estimated number and average dollar amounts of Phase I awards to be made under the solicitation.

(2) SBA will manage a searchable public database that contains all

solicitation and topic information from all SBIR/STTR Agencies. Agencies are required to update the Solicitations Database, (available at [www.SBIR.gov](http://www.SBIR.gov)), within 5 business days of a solicitation's open date for applications and/or submissions for SBCs. Refer to Appendix II (as posted on [www.SBIR.gov](http://www.SBIR.gov)) for detailed reporting requirements. The main data requirements include:

(i) Type of solicitation—SBIR/STTR;

(ii) Phase—I or II;

(iii) topic description;

(iv) sub-topic description;

(v) website for further information; and

(vi) applicable contact information per topic or sub-topic, where applicable and allowed by law.

(d) *Company Registry Database.*

(1) SBA maintains and manages a company registry to track ownership and affiliation requirements for all companies applying to the SBIR/STTR program, including those that are majority-owned by multiple VCOCs, private equity firms, or hedge funds.

(2) Each SBC applying for a Phase I or Phase II award must register on [www.SBIR.gov](http://www.SBIR.gov) prior to submitting an application. The SBC will report and/or update ownership information to SBA prior to each SBIR/STTR application submission. The SBC can view the ownership and affiliation requirements of the program on the registry site.

(3) Data collected in the Company Registry Database will not be shared publicly. Refer to Appendix II (as posted on [www.SBIR.gov](http://www.SBIR.gov)) for details on specific fields shared publicly.

(4) The SBC will save its information from the registration in a .pdf document and will append this document to the application submitted to a given agency unless the information can be transmitted automatically to SBIR/STTR Agencies.

(5) Refer to [www.SBIR.gov](http://www.SBIR.gov) for details on the required reporting fields. The main data requirements include:

(i) Basic identifying information for the SBC;

(ii) the number of employees for the SBC;

(iii) whether the SBC has venture capital, hedge fund or private equity firm investment and if so, include:

(A) The percentage of ownership of the Awardee held by the VCOC, hedge fund or private equity firm;

(B) the registration by the SBC of whether or not it is majority-owned by VCOCs, hedge funds, or private equity firms. Please note that this may be auto-populated through the individual calculations of investments in the SBC already submitted.

(iv) information on the Affiliates of the SBC, including:

(A) The names of all Affiliates of the SBC;

(B) the number of employees of the Affiliates;

(e) *Application Information Database.*

(1) SBA will manage an Application Information Database on information on applications to the SBIR/STTR program across agencies.

(2) Each agency must upload application data to the Application Information Database at [www.SBIR.gov](http://www.SBIR.gov) at least quarterly.

(3) The data in the Application Information Database is only viewable to authorized Government officials and not shared publicly.

(4) Refer to [www.SBIR.gov](http://www.SBIR.gov) for detailed reporting requirements. The main data requirements for each Phase I and Phase II application include:

(i) Name, size, and location of the Applicant, and the identifying number assigned;

(ii) an abstract and specific aims of the project;

(iii) name, title, contact information, and position in the small business of each Key Individual that will carry out the project;

(iv) percentage of effort each Key Individual identified will contribute to the project;

(v) Federal agency to which the application is made and contact information for the person responsible for reviewing applications and making awards under the program.

(5) The Application Information Database connects and cross-checks information with the Company Registry and Government personnel can see connected data.

(f) *Award Information Database.*

(1) SBA manages a database on awards made within the SBIR/STTR program across agencies.

(2) Each agency must update the Award Information Database quarterly, if not more frequently.

(3) Most of the data available on the Award Information Database is viewable and searchable by the public on [www.SBIR.gov](http://www.SBIR.gov).

(4) Refer to [www.SBIR.gov](http://www.SBIR.gov) for detailed reporting requirements. The data requirements for each Phase I and Phase II award include:

(i) Information similar to the Application Information Database—if not already collected;

(ii) the name, size, and location of, and the identifying number assigned;

(iii) an abstract and specific aims of the project;

(iv) the name, title, contact information, and position in the small business of each Key Individual that will carry out the project;

(v) the percentage of effort each identified Key Individual will contribute to the project;

(vi) the Federal agency making the award;

(vii) award amount;

(viii) Principal Investigator/Project Manager identifying information—including name, email address, and demographic information;

(ix) detailed information on location of company;

(x) whether the Awardee:

(A) Has venture capital, hedge fund or private equity firm investment and if so, the amount of such investment received by SBC as of date of award and amount of additional capital Awardee has invested in SBIR/STTR technology;

(B) is a WOSB or has a woman as a Principal Investigator/Project Manager;

(C) is an SDB or has a Socially and Economically Disadvantaged Individual as a Principal Investigator/Project Manager;

(D) is owned by a faculty member or a student of an institution of higher education as defined in 20 U.S.C. 1001); and

(E) has received the award as a result of the Commercialization Readiness Pilot Program for Civilian Agencies set forth in § 12(c) of this Policy Directive.

(xi) an identification of any business concern or subsidiary established for the commercial application of a product or service for which an SBIR or STTR award is made.

(5) The Award Information Database connects and cross-checks information with the Company Registry and Application Information Database, and Government personnel can see connected data.

(g) *Commercialization Database.*

(1) The Commercialization Database stores information reported by

Awardees on the commercial activity resulting from their past SBIR/STTR awards.

(2) Commercialization data is inputted to this database in two ways: Awardees enter their Commercialization data directly into the Commercialization Database on [www.SBIR.gov](http://www.SBIR.gov), and agencies can upload to the database at [www.SBIR.gov](http://www.SBIR.gov) Commercialization data they have collected from Awardees.

(3) The Commercialization Database is currently maintained by SBA.

(4) Awardees are required to update this information on their prior Phase II awards in the Commercialization Database when submitting an application for an SBIR/STTR Phase II award and upon completion of the last deliverable for that award.

(5) Commercialization data at the company level will not be shared publicly. Aggregated data that maintains the confidentiality of companies may be reported in compliance with the statute.

(6) Refer to [www.SBIR.gov](http://www.SBIR.gov) for the specific Commercialization data reporting fields. The main data requirements include for every Phase II award:

(i) Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR/STTR award is made;

(ii) total revenue resulting from the sale of new products or services, or licensing agreements resulting from the research conducted under each Phase II award;

(iii) additional investment received from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award;

(iv) any contract with the Federal Government marked as an SBIR/STTR Phase III award; and

(v) any narrative information that a Phase II Awardee voluntarily submits to further describe the Commercialization efforts of its awards and related research.

(7) The SBC may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award. Companies are requested to update their records in this database on a voluntary basis for at least 5 years following the completion of award.

(8) Awardees will update their information and add project Commercialization and sales data using their user names and passwords. SBA and SBIR/STTR Participating Agencies will coordinate data collection to ensure that small businesses will not need to report the same data more than once.

(9) Note that the Award Information and Commercialization Databases will contain the data necessary for agencies to determine whether an Applicant meets the agency's benchmarks for progress towards Commercialization.

(h) *Participating Agency Annual Report to SBA.*

(1) Participating Agencies must submit their report to SBA on an annual basis and will report for the period ending September 30 of each fiscal year. The report is due to SBA no later than March 15 of each year. For example, the report for FY 2017 (October 1, 2016–September 30, 2017) must be submitted to SBA by March 15, 2018.

(2) SBA provides the Annual Report form to agencies through [www.SBIR.gov](http://www.SBIR.gov). SBA reserves the right to modify the fields of the Annual Report data form beyond those identified in this directive.

(3) A number of the fields of the Annual Report template are pre-populated by SBA with data from the SBIR/STTR program database. SBA works with the agencies to resolve any data inconsistencies.

(4) The annual report includes the following:

(i) SBIR/STTR program dollars obligated through program Funding Agreements for Phase I, Phase II, and other uses of program funds, during the reporting fiscal year.

(ii) Number of topics and subtopics contained in each Program Solicitation.

(iii) Number of proposals received by the agency for each topic and subtopic in each Program Solicitation.

(iv) Agency total extramural R/R&D obligations for the reporting fiscal year including an explanation of its calculation and how it differs, if at all, from the amount reported to the NSF NCSES Survey of Federal Funds for Research and Development pursuant to the annual Budget of the United States Government.

(v) The minimum dollar amount the agency is required to obligate per fiscal year for the SBIR and STTR programs. This amount is calculated by applying the statutory per centum to the agency's total extramural R/R&D obligations made during the fiscal year (adjusted for the appropriate exclusions); and if the minimum amount was not met, the agency must provide the reasons why and an explanation of how the agency plans to meet the requirement in the future. Agencies may provide an explanation of the specific budgeting process their agency uses to allocate funds for the SBIR/STTR programs and describe any issues they may see with the compliance determination procedure. Agencies may also indicate

obligations made in the reporting year using prior fiscal years of appropriation within available funding obligation periods.

(vi) For all Applicants and Awardees in the applicable fiscal year—where applicable, the name and address, solicitation topic and subtopic, solicitation number, project title, total dollar amount of Funding Agreement, and applicable demographic information. The agency is not required to re-submit Applicant and Awardee information in the annual report that it has already reported to SBA through [www.SBIR.gov](http://www.SBIR.gov) as required.

(vii) Justification for the award of any Funding Agreement exceeding the award guidelines set forth in § 7(i) of this Policy Directive, the amount of each award exceeding the guidelines, the identity and location of the Awardee, whether the Awardee has received any venture capital, hedge fund, or private equity firm investment, and whether the Awardee is majority-owned by a venture capital operating company, hedge fund or private equity firm.

(viii) Justification for awards made under a topic or subtopic where the agency received only one proposal. Agencies must also provide the Awardee's name and address, the topic or subtopic, and the dollar amount of award. Awardee information must be collected quarterly in any case, but updated in the agency's annual reports.

(ix) All instances where the Phase II Awardee did not receive a Phase I award.

(x) All instances in which an agency pursued R/R&D, services, production, or any combination thereof of a technology developed under an SBIR/STTR award with an entity other than that Awardee. See § 10(i)(5) of this Policy Directive for minimum reporting requirements.

(xi) The number and dollar value of each SBIR/STTR and non-SBIR/STTR award (includes grants, contracts and cooperative agreements as well as any award issued under the Commercialization Programs) over \$10,000 and compare the number and amount of SBIR/STTR awards with awards to other than SBCs.

(xii) Information relating to the pilot to allow for funding of administrative, oversight, and contract processing costs, including the money spent on each activity and any other information required in the approved work plan to measure the benefits of using these funds for the specific activities—especially, as it pertains to the goals outlined in the work plan. See § 9(e)(3) of this Policy Directive concerning the Pilot to Allow for Funding of

Administrative, Oversight, and Contract Processing Costs.

(xiii) *Outreach*. A description and the extent to which the agency is increasing outreach and awards to SDBs and WOSBs.

(xiv) *VCOC-owned*. General information about the implementation of and compliance with the allocation of funds for Awardees that are majority-owned by multiple VCOCs, hedge funds or private equity firms.

(xv) *Phase III appeals*. Descriptive information on any appeals filed on Phase III awards pursuant to § 4(c)(7) of this Policy Directive and notices of noncompliance with the SBIR/STTR Policy Directive filed by SBA.

(xvi) *Phase III awards*. Information relating to each Phase III award made by that agency either as a prime or subcontract, including the name of the business receiving the Phase III award, the dollar amount, and the awarding agency or prime contractor.

(xvii) *Commercialization Programs*. An accounting of funds, initiatives, and outcomes under the commercialization programs set forth in § 12(b) and (c) of this Policy Directive.

(xviii) *Manufacturing*. Information relating to the agency's enhancement of manufacturing activities, if the agency awards more than \$50,000,000 under the SBIR and STTR programs combined in a fiscal year. The report must include:

(A) A description of efforts undertaken by the agency to enhance U.S. manufacturing activities;

(B) A comprehensive description of the actions undertaken each year by the agency in carrying out the SBIR or STTR programs to support Executive Order 13329 (relating to manufacturing);

(C) an assessment of the effectiveness of the actions taken at enhancing the R/R&D of U.S. manufacturing technologies and processes;

(D) a description of efforts by vendors selected to provide discretionary technical assistance to help SBIR and STTR business concerns manufacture in the U.S.; and

(E) recommendations from the agency's SBIR/STTR program managers/coordinators of additional actions to increase manufacturing activities in the U.S.

(ix) *Performance Areas and Metrics*. As part of agency work plans submitted pursuant to § 9(e) of this Policy Directive, SBA works with the agencies to establish the performance criteria and metrics used to measure agency performance. The Act establishes broad performance areas for the program, including Commercialization, streamlining, outreach, etc. Agencies must report their progress, using the

SBA-approved performance criteria, at the end of each fiscal year as part of the annual report. The metrics and performance areas will evolve over time and can be found at [www.SBIR.gov](http://www.SBIR.gov).

(i) *Other Reporting Requirements*.

(1) SBA will set forth a list of reports that agencies are required by statute to submit, in a table format, which will be available at [www.SBIR.gov](http://www.SBIR.gov).

(2) SBA's SBIR/STTR program database will include a list of any individual or SBC that has received an SBIR/STTR award and that has been convicted of a fraud-related crime involving SBIR/STTR funds or found civilly liable for a fraud-related violation involving SBIR/STTR funds, of which SBA has been made aware.

(3) Program Funding Compliance.

Agencies must submit to SBA's Administrator, not later than 4 months after the date of enactment of its annual Appropriations Act, a report on the agency's plan to meet the program funding requirement for the current fiscal year. SBA provides detailed guidance regarding this report on [www.SBIR.gov](http://www.SBIR.gov).

The report must include the following main elements:

(A) An explanation of the calculation of total extramural R/R&D including an itemization of each research program excluded from the calculation including the dollar amount and a brief explanation of why it is excluded,

(B) a review of the agency's compliance with the funding requirement in the prior fiscal year to determine if the program funding process enabled the agency to meet the requirement, and

(C) a funding plan showing how the agency is budgeting its funds for the SBIR/STTR programs during the current fiscal year so as to meet or exceed the year's expected minimum obligations requirement for the program.

(4) Agencies must provide notice to SBA of any case or controversy before any Federal judicial or administrative tribunal concerning the SBIR/STTR program of the Federal agency. This does not include agency level protests of awards unless and until the protest is before a Federal court or administrative body. The agency must provide notice to SBA within 15 business days of the agency's written notification of the case or controversy.

(5) Agencies must provide notice of all instances in which an agency pursued research, development, production, or any such combination of a technology developed by an SBC using an award made under the SBIR/STTR program of that agency, where the agency determined that it was not

practicable to enter into a follow-on non-SBIR/STTR Funding Agreement with that concern. The agency must provide notice to SBA within 15 business days of the agency's award.

The report must include, at a minimum:

- (i) The reasons why the follow-on Funding Agreement with the concern was not practicable;
- (ii) the identity of the entity with which the agency contracted to perform the research, development, or production; and
- (iii) a description of the type of Funding Agreement under which the research, development, or production was obtained.

(6) Participating Agencies must provide information supporting the agency's achievement of the Interagency Policy Committee's policy recommendations on ways to improve program effectiveness and efficiency. This includes qualitative and quantitative data as appropriate, which would measure the agency's progress. The agency must provide this information to SBA at the end of each fiscal year.

(7) Participating Agencies must provide an annual report to SBA, Senate Committee on Small Business and Entrepreneurship, House Committee on Small Business, and the House Committee on Science, Space, and Technology on SBIR and STTR programs and the benefits of these programs to the United States. Prior to preparing the report, the agency shall develop metrics to evaluate the effectiveness and benefit to the United States of the SBIR and STTR programs. The metrics must be science-based and statistically driven, reflect the mission of the agency, and include factors relating to the economic impact of the programs. The report must describe in detail the agency's annual evaluation of the programs using these metrics. The final report must be posted online so it can be made available to the public.

(8) NIH, DoD and the DoEd must provide the written determination to SBA any time it issues a Phase II award to an SBC that did not receive a Phase I award for that R/R&D. The determination must be submitted prior to award.

(9) SBA will compile data and report to Congress on the Federal and State Technology (FAST) Partnership Program, described in § 12 of this Policy Directive. If required by the FAST grant, the grantees will report a comprehensive list of the companies that received assistance under FAST, whether those companies received SBIR or STTR awards, and any information regarding mentors and Mentoring

Networks, as required in the FAST Partnership Program.

(j) *Further Clarification on Availability of SBC Information.*

(1) Unless stated otherwise, the information contained in the Company Registry Database, the Application Information Database, and the Commercialization Database is solely available to authorized Government officials, with the approval of SBA. This includes Congress, the Government Accountability Office (GAO), the SBIR/STTR Participating Agencies, Office of Management and Budget (OMB), OSTP, OFPP, and other authorized persons who are subject to an NDA with the Federal Government covering the use of the databases. These databases are used for the purposes of evaluating and determining eligibility for the SBIR/STTR program, in accordance with Policy Directives issued by SBA. Pursuant to 15 U.S.C. 638(k)(4), certain information provided to those databases is privileged and confidential and not subject to disclosure pursuant to 5 U.S.C. 552 (Government Organization and Employees); nor must it be considered to be publication for purposes of 35 U.S.C. 102(a) or (b).

(2) Most of the information in the Award Information and Annual Reports Databases will be available to the public. Any information that will identify the confidential business information of a given SBC will not be disclosed to the public. Those databases are available at [www.SBIR.gov](http://www.SBIR.gov) and offer a vast array of user-friendly capabilities that are accessible by the public at no charge. The Award Information Database allows for the online submission of SBIR/STTR awards data from all SBIR/STTR Agencies. It also allows any end-user to perform keyword searches and create formatted reports of SBIR/STTR awards information, and for potential research partners to view research and development efforts that are ongoing in the SBIR and the STTR programs, increasing the investment opportunities of the SBIR/STTR SBCs in the high tech arena.

(k) *Waivers.*

(1) Participating Agencies must request an extension for additional time between the solicitation closing date and notification of recommendation for award. SBA will respond to the request for an extension within 5 business days, as practicable. See § 7(c)(1) of this Policy Directive for further information.

(2) Participating Agencies must request a waiver to exceed the award guidelines for Phase I and Phase II awards by more than 50% for a specific topic. See § 7(i)(4) of this Policy Directive for further information.

(3) Participating Agencies must request a waiver to not use their SBIR funds, as part of the pilot allowing for the use of such funds for certain SBIR-related costs, to increase participation by SDBs and WOSBs in the SBIR/STTR program, and small businesses in states with a historically low level of SBIR/STTR awards. See § 9(e)(3)(ii) of this Policy Directive for further information.

(4) Participating Agencies must request a waiver to issue a Funding Agreement that includes a provision for subcontracting a portion of that agreement back to the issuing agency if there is no exception to this requirement in the directive. See § 9(e)(4) of this Policy Directive for further information.

**11. Responsibilities of SBA**

(a) *Policy.*

(1) SBA establishes policy and procedures for the program by publishing and updating the SBIR/STTR Policy Directive and promulgating regulations. Policy clarification of any part or provision of the directive or regulations may be provided by SBA.

(2) It is essential that SBIR/STTR Agencies do not promulgate any policy, rule, regulation, or interpretation that is inconsistent with the Act, this Policy Directive, or SBA's regulations relating to the SBIR/STTR program. SBA's monitoring activity will include review of policies, rules, regulations, interpretations, and procedures generated to facilitate intra- and interagency SBIR/STTR program implementation.

(3) Waivers providing limited exceptions to certain policies can be found at § 10(k) of this Policy Directive.

(b) *Outreach.* SBA conducts outreach to achieve a number of objectives including:

(1) Educating the public about the SBIR/STTR programs via conferences, seminars, and presentations;

(2) Highlighting the successes achieved in the program by publishing (via press releases and [www.SBIR.gov](http://www.SBIR.gov)) success stories, as well as hosting awards programs;

(3) Maintaining [www.SBIR.gov](http://www.SBIR.gov), which is an online public information resource that provides comprehensive information regarding the SBIR/STTR programs. This information includes: a listing of solicitation information on currently available SBIR/STTR opportunities, award information on all Phase I and Phase II awards, summary annual award information for the whole program, and contact information for SBA and SBIR/STTR program managers/coordinators.

(c) *Collection and publication of program-wide data.* SBA collects and

maintains program-wide data within the *www.SBIR.gov* data system. This data includes information on all Phase I and II awards from across all SBIR/STTR Agencies, as well as fiscal year Annual Report data. See § 10 of this Policy Directive for further information about reporting and data collection requirements.

(d) *Monitoring implementation of the program and annually reporting to Congress.* SBA is responsible for providing oversight and monitoring the implementation of the SBIR/STTR programs at the agency level. This monitoring includes:

(1) *SBIR/STTR Funding Allocations.* The Act establishes the source of the funds for the SBIR/STTR programs (extramural R/R&D), the percentage of such funds to be obligated through the SBIR and STTR programs, and it requires that SBA monitor these annual allocations. Participating Agencies may include in their annual report to SBA an explanation of the specific budgeting process used to allocate funds to the SBIR/STTR programs and describe any issues observed with the compliance determination process.

(2) *SBIR/STTR Program Solicitation and Award Status.* The accomplishment of scheduled SBIR/STTR events, such as SBIR/STTR Program Solicitation releases and the issuance of Funding Agreements is critical to meeting statutory mandates and to operating an effective, useful program. SBA monitors these and other operational features of the SBIR/STTR programs and publishes information relating to notice of and application for awards under the SBIR/STTR programs for each SBIR/STTR Participating Agency at *www.SBIR.gov*. SBA does not plan to monitor administration of the awards except in instances where SBA assistance is requested and is related to a specific SBIR/STTR project or Funding Agreement.

(3) *Follow-on Funding Commitments.* SBA will monitor whether follow-on non-Federal funding commitments obtained by Phase II Awardees for Phase III were considered in the evaluation of Phase II proposals as required by the Act.

(4) *Fraud, Waste, and Abuse (FWA).* SBA will ensure that each SBIR/STTR Participating Agency has taken steps to maintain a FWA prevention system to minimize its impact on the programs.

(5) *Performance Areas, Metrics, and Goals.* SBA is responsible for defining performance areas consistent with statute (e.g., reducing timelines for awards, simplification) against which agencies will set goals. SBA will work with the Participating Agencies to set

metrics, in order to measure an agency's accomplishments of its goals against the defined performance areas. The purpose of these metrics and goals is to assist SBA in evaluating and reporting on the progress achieved by the agencies in improving the SBIR/STTR programs. For further information on Performance Areas, Metrics and Goals see § 10(h) of this Policy Directive.

(e) *Additional efforts to improve the performance of the program.* SBA, in its continuing effort to improve the program, will make recommendations for improvement within the framework of the SBIR/STTR program managers/coordinators' meetings. This may include recommending a "best practice" currently being utilized by an agency or business, or open discussion and feedback on a potential "best practice" for agency adoption. This may also involve program-wide initiatives.

(f) *Federal and State Technology (FAST) Partnership Program.* SBA coordinates and administers the FAST program. SBA develops the solicitation, reviews proposals, and oversees grant awards. FAST provides grantees with funding to assist in outreach, proposal preparation, and other technical assistance to developing innovation-oriented SBCs.

## 12. Supporting Programs and Initiatives

(a) *Federal and State Technology (FAST) Partnership Program.* The purpose of the FAST program is to strengthen the technological competitiveness of SBCs in the United States. Congress found that programs that foster economic development among small high-technology firms vary widely among the states. Thus, the purpose of the FAST program is to improve the participation of small technology firms in the innovation and Commercialization of new technologies, thereby ensuring that the United States remains on the cutting-edge of research and development in the highly competitive arena of science and technology. Additional and detailed information regarding this program is available at *www.SBIR.gov*.

(b) *Commercialization Readiness Program (CRP)—DoD.*

(1) *General.* The Secretary of Defense and the Secretary of each military department is authorized to create and administer the Commercialization Readiness Program (CRP) to accelerate the transition of technologies, products, and services developed under the SBIR program to Phase III, including the acquisition process. The authority for CRP does not eliminate or replace any other SBIR or STTR program that enhances the insertion or transition of

SBIR or STTR technologies. This includes any program in effect as of December 31, 2011.

(2) *Identification of research programs for accelerated transition to acquisition process.* The Secretary of each military department must identify research programs of the SBIR or STTR program that have the potential for rapid transitioning to Phase III and into the acquisition process and certify in writing that the successful transition of the program to Phase III and into the acquisition process is expected to meet high priority military requirements of such military department.

(3) *Limitation.* The Secretary of Defense shall identify research programs of the SBIR or STTR program that have the potential for rapid transitioning to Phase III and into the acquisition process after receiving this certification from each military department.

(4) *Funding.*

(i) The Secretary of Defense and each Secretary of a military department is authorized to use its SBIR funds for administration of CRP in accordance with the procedures and policies set forth in § 9(e)(3) of this Policy Directive.

(ii) In addition, the Secretary of Defense and Secretary of each military department is authorized to use not more than an amount equal to 1% of its SBIR funds available to DoD or the military departments for payment of expenses incurred to administer the CRP. Such funds—

(A) shall not be subject to the limitations on the use of funds in 9(e)(2) or 9(e)(3) of this Policy Directive; and

(B) shall not be used to make Phase III awards.

(5) *Contracts Valued at not less than \$100,000,000.* For any contract awarded by DoD valued at not less than \$100,000,000, the Secretary of Defense may:

(i) Establish goals for the transition of Phase III technologies in subcontracting plans; and

(ii) require a prime contractor on such a contract to report the number and dollar amount of the contracts entered into by the prime contractor for Phase III projects.

(6) The Secretary of Defense shall:

(i) Set a goal to increase the number of SBIR/STTR Phase II contracts that lead to technology transition into programs of record of fielded systems;

(ii) use incentives in effect as of December 31, 2011 or create new incentives to encourage agency SBIR/STTR program managers/coordinators and prime contractors to meet the goal set forth in paragraph (6)(i) above; and

(iii) submit the following to SBA, as part of the annual report:

(A) The number and percentage of Phase II SBIR/STTR contracts awarded by DoD that led to technology transition into programs of record or fielded systems;

(B) information on the status of each project that received funding through the CRP and the efforts to transition these projects into programs of record or fielded systems; and

(C) a description of each incentive that has been used by DoD, the effectiveness of the incentive with respect to meeting DoD's goal to increase the number of SBIR/STTR Phase II contracts that lead to technology transition into programs of record or fielded systems, and measures taken to ensure that such incentives do not act to shift the focus of Phase II awards away from relatively high-risk innovation projects.

(c) *Commercialization Readiness Pilot Program for Civilian Agencies.*

(1) *General.* The Commercialization Readiness Pilot Program permits the head of any Federal Agency participating in the SBIR program (except DoD) to allocate not more than 10% of its funds allocated to the SBIR program—

(i) for follow-on awards to small businesses for technology development, testing, evaluation, and Commercialization assistance for SBIR or STTR Phase II technologies; or

(ii) for awards to small businesses to support the progress of research, research and development, and Commercialization conducted under the SBIR or STTR programs to Phase III.

(2) *Application to SBA.* Before establishing this pilot program, the agency must submit a written application to SBA not later than 90 days before the first day of the fiscal year in which the pilot program is to be established. The written application must set forth a compelling reason that additional investment in SBIR or STTR technologies is necessary, including unusually high regulatory, systems integration, or other costs relating to development or manufacturing of identifiable, highly promising small business technologies or a class of such technologies expected to substantially advance the mission of the agency.

(3) *SBA's Determination.* SBA must make its determination regarding an application submitted under paragraph (c)(2) above not later than 30 days before the first day of the fiscal year for which the application is submitted. SBA must also publish its determination in the **Federal Register** and make a copy of the determination and any related materials available to the Committee on Small Business and Entrepreneurship of the

Senate and the Committee on Small Business and the Committee on Science, Space, and Technology of the House of Representatives.

(4) *Maximum Amount of Award.* The SBIR agency may not make an award to an SBC under this pilot program in excess of 3 times the dollar amounts generally established for Phase II awards under § 7(i)(1) of this Policy Directive.

(5) *Registration.* Any SBC that receives an award under this pilot program shall register with SBA in the Company Registry Database.

(6) *Award Criteria or Consideration.* When making an award under this pilot program, the agency is required to consider whether the technology to be supported by the award is likely to be manufactured in the United States.

(7) *Termination of Authority.* The authority to establish a pilot program under this section expires on September 30, 2022, unless otherwise extended.

(d) *Technology Development Program.* The Act permits an agency that has established a Technology Development Program to review for funding under that program, in each fiscal year:

(1) any proposal to provide outreach and assistance to 1 or more SBCs interested in participating in the SBIR program, including any proposal to make a grant or loan to a company to pay a portion or all of the cost of developing an SBIR proposal, from an entity, organization, or individual located in—

(i) a State that is eligible to participate in that Technology Development Program; or

(ii) an Additionally Eligible State.

(2) any meritorious proposal for an SBIR Phase I award that is not funded through the SBIR program for that fiscal year due to funding constraints, from an SBC located in a State identified in (i) or (ii) immediately above.

(e) [STTR only] *Phase 0 Proof of Concept Partnership Pilot Program.*

(1) *General.* The Director of NIH may use \$5,000,000 of the funds allocated for the STTR program set forth in § 2(b) of this Policy Directive for a Proof of Concept Partnership Pilot Program to accelerate the creation of small businesses and the Commercialization of research innovations from qualifying institutions. A qualifying institution is a university or other Research Institution that participates in the NIH's STTR program. The Director shall award, through a competitive, merit-based process, grants to qualifying institutions in order to implement this program. These grants shall only be used to administer Proof of Concept Partnership awards.

(2) *Awards to Qualifying Institutions.*

(i) The Director may make awards to a qualifying institution for up to \$1,000,000 per year for up to 4 years.

(ii) In determining which qualifying institutions will receive pilot program grants, the Director of NIH shall consider, in addition to any other criteria the Director determines necessary, the extent to which qualifying institutions—

(A) have an established and proven technology transfer or commercialization office and have a plan for engaging that office in the program's implementation;

(B) have demonstrated a commitment to local and regional economic development;

(C) are located in diverse geographies and are of diverse sizes;

(D) can assemble project management boards comprised of industry, start-up, venture capital, technical, financial, and business experts;

(E) have an Intellectual Property rights strategy or office; and

(F) demonstrate a plan for sustainability beyond the duration of the funding award.

(3) *Proof of Concept Partnerships.* A qualifying institution selected by NIH shall establish a Proof of Concept Partnership with NIH to award grants to individual researchers. These grants should provide researchers with the initial investment and the resources to support the proof of concept work and Commercialization mentoring needed to translate promising research projects and technologies into a viable company. This work may include technical validations, market research, clarifying Intellectual Property rights position and strategy, and investigating commercial or business opportunities.

(4) *Award Guidelines.* The administrator of a Proof of Concept Partnership program shall award grants in accordance with the following guidelines:

(i) The Proof of Concept Partnership shall use a market-focused project management oversight process, including—

(A) a rigorous, diverse review board comprised of local experts in translational and proof of concept research, including industry, start-up, venture capital, technical, financial, and business experts and university technology transfer officials;

(B) technology validation milestones focused on market feasibility;

(C) simple reporting effective at redirecting projects; and

(D) the willingness to reallocate funding from failing projects to those with more potential.

(ii) The Proof of Concept Partnership shall not award more than \$100,000 towards an individual proposal.

(5) *Educational Resources and Guidance.* The administrator of a Proof of Concept Partnership program shall make educational resources and guidance available to researchers attempting to commercialize their innovations.

(6) *Limitations.*

(i) The funds for the pilot program shall not be used for basic research or to fund the acquisition of research equipment or supplies unrelated to Commercialization activities.

(ii) The funds for the pilot program can be used to evaluate the commercial potential of existing discoveries, including proof of concept research or Prototype development; and activities that contribute to determining a project's Commercialization path, to include technical validations, market research, clarifying Intellectual Property rights, and investigating commercial and business opportunities.

(7) *Termination of Authority.* The pilot program under this subsection shall terminate on September 30, 2022, unless otherwise extended.

#### Appendix I: Instructions for SBIR and STTR Program Solicitation Preparation

a. *General.* Subsections 9(j) and 9(p) of the Act (15 U.S.C. 638(j)) require simplified, standardized and timely SBIR/STTR solicitations and for SBIR/STTR Participating Agencies to utilize a "uniform process" minimizing the regulatory burden of participation. Therefore, the following instructions purposely depart from normal Government solicitation formats and requirements. SBIR/STTR solicitations must be prepared and issued as Program Solicitations in accordance with the following instructions.

b. *Limitation in Size of Solicitation.* In the interest of meeting the requirement for simplified and standardized solicitations, while also recognizing that the internet has become the main vehicle for distribution, each agency should structure its entire SBIR/STTR solicitation to produce the least number of pages (electronic and printed), consistent with the procurement/assistance standard operating procedures and statutory requirements of the Participating Agencies.

c. *Format.* SBIR/STTR Program Solicitations must be prepared in a simple, standardized, easy-to-read, and easy-to-understand format. It must include a cover sheet, a table of contents, and the following sections in the order listed.

1. Program Description

2. Certifications
3. Proposal Preparation Instructions and Requirements
4. Method of Selection and Evaluation Criteria
5. Considerations
6. Submission of Proposals
7. Scientific and Technical Information Sources
8. Submission Forms
9. Research Topics

d. *Cover Sheet.* The cover sheet of an SBIR/STTR Program Solicitation must clearly identify the solicitation as an SBIR/STTR solicitation, identify the agency releasing the solicitation, specify date(s) on which contract proposals or grant applications are due under the solicitation, and state the solicitation number or year.

e. *Instructions for Preparation of SBIR or STTR Program Solicitation—Sections 1–9.*

§ 1. *Program Description.*

(a) Summarize in narrative form the request for proposals and the objectives of the SBIR or STTR program.

(b) Describe in narrative form the agency's SBIR or STTR program including a description of the three phases. Note in your description whether the solicitation is for Phase I or Phase II proposals. Also note in each solicitation for Phase I that all Awardees may apply for a Phase II award and provide guidance on the procedure for doing so.

(c) Describe program eligibility.

(d) List the name, address and telephone number of agency contacts for general information on the SBIR or STTR Program Solicitation.

(e) Whenever terms are used that are unique to the SBIR or STTR program, a specific SBIR or STTR solicitation or a portion of a solicitation, define them or refer potential offerors/Applicants to a source for the definition. At a minimum, the definitions of "Funding Agreement," "R/R&D," "SBC," "SBIR/STTR Data," and "SBIR/STTR Data Rights" must be included.

(f) Include information explaining how an individual can report fraud, waste and abuse (e.g. include the fraud hotline for the agency's Office of Inspector General);

§ 2. *Certifications.*

(a) This section must include certifying forms required by legislation, regulation or standard operating procedures, to be submitted by the Applicant to the contracting or granting agency. This would include certifying forms such as those for the protection of human and animal subjects.

(b) This section must include any certifications required concerning size,

ownership and other SBIR or STTR program requirements.

(i) The agency may request the SBIR/STTR Applicant to submit a certification at the time of submission of the application or offer. The certification may require the Applicant to state that it intends to meet the size, ownership and other requirements of the SBIR or STTR program at the time of award of the Funding Agreement, if selected for award.

(ii) The agency must request the Applicant to submit a certification at the time of award and at any other time set forth in SBA's regulations at 13 CFR 121.701–121.705. The certification will require the Applicant to state that it meets the size, ownership and other requirements of the SBIR or STTR program at the time of award of the Funding Agreement.

(iii) The agency must request the Awardee to submit certifications during the Funding Agreement life cycle. A Phase I Funding Agreement must state that the Awardee shall submit a new certification that it is in compliance with specific SBIR or STTR program requirements at the time of final payment or disbursement. A Phase II Funding Agreement must state that the Awardee shall submit a new certification that it is in compliance with specific SBIR or STTR program requirements prior to receiving more than 50% of the total award amount and prior to final payment or disbursement.

(iv) Agencies may require additional certifications at other points in time during the life cycle of the Funding Agreement, such as at the time of each payment or disbursement.

(c) The agency must use the following certification at the time of award and upon notification by SBA, must check [www.SBIR.gov](http://www.SBIR.gov) for updated certifications prepared by SBA:

#### *SBIR/STTR Funding Agreement Certification*

All small businesses that are selected for award of an SBIR/STTR Funding Agreement must complete this certification at the time of award and any other time set forth in the Funding Agreement that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the Awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal Government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) program or Small Business Technology Transfer (STTR)

program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the Funding Agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 CFR part 121), the SBIR/STTR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the Funding Agreement officer believes that the business may not meet certain eligibility requirements at the

time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), which will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Funding Agreement officer believes, after award, that the business is not meeting certain Funding Agreement requirements, the agency may request further clarification and supporting documentation in order to

assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal Government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

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The undersigned has reviewed, verified and certifies that (*all boxes must be checked unless otherwise directed*):

(1)  The Awardee business concern meets the ownership and control requirements set forth in 13 CFR 121.702.

(2) If a corporation – all corporate documents (namely: articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) must evidence that the corporation meets the ownership and control requirements set forth in 13 CFR 121.702. (Check one box).

Yes       N/A Explain why N/A:

(3) If a partnership -- the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 CFR 121.702. (Check one box).

Yes       N/A Explain why N/A:

(4) If a limited liability company – the articles of organization and any amendments, and operating agreement and amendments, evidence that it meets the ownership and control requirements set forth in 13 CFR 121.702. (Check one box).

Yes       N/A Explain why N/A:

(5) The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States. (Check one box).

Yes     N/A    Explain why N/A:

(6)  The Awardee business concern has no more than 500 employees, including the employees of its Affiliates.

(7)  SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard.

(8) During the performance of the award, the Principal Investigator/Project Manager will spend more than one half of his/her time (based on a 40 hour workweek) as an employee of the Awardee (or Research Institution – STTR only) or has requested and received a written deviation from this requirement from the Funding Agreement officer. (Check one box).

Yes     Deviation approved in writing by Funding Agreement officer: \_%

(9) All Essentially Equivalent Work, or a portion of the work, proposed under this project (check applicable line):

**Has not** been submitted for funding to this Agency or another Federal agency.

**Has** been submitted for funding to this Agency or another Federal agency **but has not** been funded under any other grant, contract, subcontract or other transaction.

A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Funding Agreement officer.

(10) During performance of award, the Awardee will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Funding Agreement officer (check applicable line and fill in if needed):

SBIR Phase I: at least two-thirds (66 2/3%) of the research.

SBIR Phase II: at least half (50%) of the research.

STTR Phase I or Phase II: at least forty percent (40%) of the research.

Deviation approved in writing by the Funding Agreement officer (SBIR only):

\_\_%

(11) During performance of award, the R/R&D will be performed in the United States unless a deviation is approved in writing by the Funding Agreement officer (check one box).

Yes       Waiver has been granted

(12)  During performance of award, the R/R&D will be performed at the Awardee's facilities by the Awardee's employees, except as otherwise indicated in the SBIR/STTR application and approved in the Funding Agreement.

(13) The SBIR Awardee has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms (check one box).

Yes       No       N/A Explain why N/A: \_\_\_\_\_

(14) The SBIR Awardee is a Covered Small Business Concern (a Small Business Concern that: (a) was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on the date on which it submitted an application in response to an SBIR solicitation; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the solicitation, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms). (Check one box).

Yes       No

(15)  I will notify this Agency immediately if all or a portion of the work authorized and funded under this award is subsequently funded by another Federal Agency.

(16) [*For STTR only*] The Small Business Concern, and not a partnering Research Institution, is exercising management direction and control of the performance of the STTR Funding Agreement.

Yes       No

(17)  I understand that the information submitted may be given to Federal, State, and local agencies for determining violations of law and other purposes.

(18)  I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 et seq.); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

<i>Signature</i>	<i>Date</i> __/__/__
<i>Print Name (First, Middle, Last)</i>	
<i>Title</i>	
<i>Business Name</i>	

(d) The agency must use the following certification during the life cycle of the Funding Agreement in accordance with subsection 8(j) of the SBIR/STTR Policy Directive and paragraph 2(b)(iii) of this Appendix and upon notification by SBA, must check [www.SBIR.gov](http://www.SBIR.gov) for updated certifications prepared by SBA:

*SBIR/STTR Funding Agreement Certification—Life Cycle Certification*

All SBIR/STTR Phase I and Phase II Awardees must complete this certification at all times set forth in the Funding Agreement (*see* § 8(j) of the SBIR/STTR Policy Directive). This includes checking all of the boxes (unless otherwise directed) and having

an authorized officer of the Awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal Government relies on the information to ensure compliance with specific program requirements during the life of the Funding Agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, the SBIR/STTR Policy Directive, and also any statutory and regulatory provisions referenced in those authorities.

If the Funding Agreement officer believes that the business is not meeting

certain Funding Agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal Government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked except where otherwise directed):

(1) The Principal Investigator/Project Manager spent more than one half of his/her time (based on a 40 hour workweek) as an employee of the Awardee (or Research Institution – STTR only) or the Awardee has requested and received a written deviation from this requirement from the Funding Agreement officer.

Yes  No  Deviation approved in writing by Funding Agreement officer: \_\_\_%

(2) All Essentially Equivalent Work, or a portion of the work, performed under this project (check the applicable line):

**Has not** been submitted for funding to this Agency or another Federal Agency.

**Has** been submitted for funding to this Agency or another Federal agency **but has not** been funded under any other grant, contract, subcontract or other transaction.

A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Funding Agreement officer.

(3) Upon completion of the award, the Awardee will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Funding Agreement officer (check the applicable line and fill in if needed):

SBIR Phase I: at least two-thirds (66 2/3%) of the research.

SBIR Phase II: at least half (50%) of the research.

STTR Phase I or Phase II: at least forty percent (40%) of the research.

Deviation approved in writing by the Funding Agreement officer (SBIR only):

\_\_\_%

(4) The work is completed and the small business Awardee has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Funding Agreement officer (check the applicable line and fill in if needed):

- SBIR Phase I: at least two-thirds (66 2/3%) of the research.
- SBIR Phase II: at least half (50%) of the research.
- STTR Phase I or Phase II: at least forty percent (40%) of the research.
- Deviation approved in writing by the Funding Agreement officer: \_\_\_%
- N/A because work is not completed

(5) [For STTR only] The Small Business Concern, and not a partnering Research Institution, is exercising management direction and control of the performance of the STTR Funding Agreement.

- Yes       No

(6) The R/R&D is performed in the United States unless a deviation is approved in writing by the Funding Agreement officer.

- Yes       No       Waiver has been granted

(7) The R/R&D is performed at the Awardee's facilities by the Awardee's employees, except as otherwise indicated in the SBIR/STTR application and approved in the Funding Agreement.

- Yes       No

(8)  I will notify this Agency immediately if all or a portion of the work authorized and funded under this award is subsequently funded by another Federal Agency.

(9)  I understand that the information submitted may be given to Federal, State, and local agencies for determining violations of law and other purposes.

(10)  I am an officer of the Awardee business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern, that the information provided in this certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. 3729 *et seq.*); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 *et seq.*); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

<i>Signature</i>	<i>Date</i> __/__/__
<i>Print Name (First, Middle, Last)</i>	
<i>Title</i>	
<i>Business Name</i>	

(e) [SBIR only] The agency must require any SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms to submit the following certification with its SBIR application:

*Certification for SBIR Applicants That Are Majority-Owned by Multiple Venture Capital Operating Companies, Hedge Fund or Private Equity Firms*

Any small business that is majority-owned by multiple venture operating companies (VCOCs), hedge funds, or

private equity firms and is submitting an application for an SBIR Funding Agreement must complete this certification prior to submitting an application. This includes checking all of the boxes and having an authorized officer of the Applicant sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal Government relies on the information to determine whether the business is eligible for a Small Business Innovation

Research (SBIR) program award and meets the specific program requirements during the life of the Funding Agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 CFR part 121), the SBIR/STTR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the Funding Agreement officer believes that the business may not meet certain eligibility requirements at the time of award, he/she is required to file

a size protest with the U.S. Small Business Administration (SBA), which will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Funding Agreement officer believes, after award, that the

business is not meeting certain Funding Agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal Government, any action

taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (*all boxes must be checked*):

(1)  The Applicant is NOT more than 50% owned by a single VCOC, hedge fund, or private equity firm.

(2)  The Applicant is more than 50% owned by multiple domestic business concerns that are VCOCs, hedge funds, or private equity firms.

(3)  I have registered with SBA at [www.SBIR.gov](http://www.SBIR.gov) as a business that is majority-owned by multiple VCOCs, hedge funds or private equity firms.

(4)  I understand that the information submitted may be given to Federal, State, and local agencies for determining violations of law and other purposes.

(5)  All the statements and information provided in this form and any documents submitted are true, accurate, and complete. If assistance was obtained in completing this form and the supporting documentation, I have personally reviewed the information and it is true and accurate. I understand that, in general, these statements are made for the purpose of determining eligibility for an SBIR Funding Agreement and continuing eligibility.

(6)  I understand that the certifications in this document are continuing in nature. Each SBIR Funding Agreement for which the small business submits an offer or application or receives an award constitutes a restatement and reaffirmation of these certifications.

(7)  I understand that I may not misrepresent status as small business to: 1) obtain a contract under the Act; or 2) obtain any benefit under a provision of Federal law that references the SBIR program.

(8)  I am an *officer* of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the SBIR Applicant or Awardee, that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. 3729 *et seq.*); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 *et seq.*); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

<i>Signature</i>	<i>Date</i> __/__/__
<i>Print Name (First, Middle, Last)</i>	
<i>Title</i>	
<i>Business Name</i>	

## BILLING CODE 8025-01-C

§ 3. *Proposal Preparation Instructions and Requirements.* The purpose of this section is to inform the Applicant on what to include in the proposal and to set forth limits on what may be included. It should also provide guidance to assist Applicants, particularly those that may not have previous Government experience, in

improving the quality and acceptance of proposals.

(a) *Limitations on Length of Proposal.* Include at least the following information:

(1) SBIR/STTR Phase I proposals must not exceed a total of 25 pages, including cover page, budget, and all enclosures or attachments, unless stated otherwise in the agency solicitation. Pages should be of standard size (8 1/2" x 11"; 21.6 cm

x 27.9 cm) and should conform to the standard formatting instructions. Margins should be 2.5 cm and type at least 10 point font.

(2) A notice that no additional attachments, appendices, or references beyond the 25-page limitation shall be considered in proposal evaluation (unless specifically solicited by an agency) and that proposals in excess of

the page limitation shall not be considered for review or award.

(b) *Proposal Cover Sheet*. Every Applicant is required to provide a copy of its registration information printed from the Company Registry unless the information can be transmitted automatically to SBIR/STTR Participating Agencies. Every Applicant must also include at least the following information on the first page of proposals. Items 8 and 9 are for statistical purposes only.

(1) Agency and Program Solicitation Number or Year.

(2) Topic Number or Letter.

(3) Subtopic Number or Letter.

(4) Topic Area.

(5) Project Title.

(6) Name and Complete Address of SBC.

(7) Disclosure permission (by statement or checkbox), such as follows, must be included at the discretion of the funding agency:

“Will you permit the Federal Government to disclose the name, address, and telephone number of the corporate official of your concern, if your proposal does not result in an award, to appropriate local and State-level economic development organizations that may be interested in contacting you for further information?  
 Yes  No”

(8) Signature of a company official of the proposing Small Business Concern and that individual's typed name, title, address, telephone number, and date of signature.

(9) Signature of Principal Investigator or Project Manager within the proposing Small Business Concern and that individual's typed name, title, address, telephone number, and date of signature.

(10) Legend for proprietary information as described in the “Considerations” section of this Program Solicitation if appropriate. This may also be noted by asterisks in the margins on proposal pages.

(c) *Data Collection Requirement*.

(1) Each Phase I and Phase II Applicant is required to provide information for SBA's database ([www.SBIR.gov](http://www.SBIR.gov)). The following are examples of the data to be entered by Applicants into the database:

(i) Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR or STTR award is made.

(ii) Revenue from the sale of new products or services resulting from the research conducted under each Phase II award;

(iii) Additional investment from any source, other than Phase I or Phase II

awards, to further the research and development conducted under each Phase II award.

(iv) Update the information in the database for any prior Phase II award received by the SBC. The SBC may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award.

(2) Each Phase II Awardee is required to update the appropriate information on the award in the database upon completion of the last deliverable under the Funding Agreement and is requested to voluntarily update the information in the database annually thereafter for a minimum period of 5 years.

(d) *Abstract or Summary*. Applicants will be required to include a one-page project summary of the proposed R/R&D including at least the following:

(1) Name and complete address of SBC.

(2) Name and title of Principal Investigator/Project Manager.

(3) Participating Agency name, Program Solicitation number, and Program Solicitation topic and subtopic.

(4) Title of project.

(5) Technical abstract limited to two hundred words.

(6) Summary of the anticipated results and implications of the approach (both Phases I and II) and the potential commercial applications of the research.

(e) *Technical Content*. SBIR or STTR Program Solicitations must require, as a minimum, the following to be included in proposals submitted thereunder:

(1) *Identification and Significance of the Problem or Opportunity*. A clear statement of the specific technical problem or opportunity addressed.

(2) *Phase I Technical Objectives*. State the specific objectives of the Phase I research and development effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

(3) *Phase I Work Plan*. Include a detailed description of the Phase I R/R&D plan. The plan should indicate what will be done, where it will be done, and how the R/R&D will be carried out. Phase I R/R&D should address the objectives and the questions cited in (e)(2) immediately above. The methods planned to achieve each objective or task should be discussed in detail.

(4) *Related R/R&D*. Describe significant R/R&D that is directly related to the proposal, including any conducted by the Principal Investigator/Project Manager or by the proposing SBC. Describe how it relates to the proposed effort, and any planned

coordination with outside sources. The Applicant must persuade reviewers of his or her awareness of key, recent R/R&D conducted by others in the specific topic area.

(5) *Key Individuals and Bibliography of Directly Related Work*. Identify Key Individuals involved in Phase I including their directly-related education, experience, and bibliographic information. Where vitae are extensive, summaries that focus on the most relevant experience or publications are desired and may be necessary to meet proposal size limitation.

(6) *Relationship with Future R/R&D*.

(i) State the anticipated results of the proposed approach if the project is successful (Phase I and II).

(ii) Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

(7) *Facilities*. A detailed description, availability and location of instrumentation and physical facilities proposed for Phase I should be provided.

(8) *Consultants*. Involvement of consultants in the planning and research stages of the project is permitted. If such involvement is intended, it should be described in detail.

(9) *Potential Post Applications*. Briefly describe:

(i) Whether and by what means the proposed project appears to have potential commercial application.

(ii) Whether and by what means the proposed project appears to have potential use by the Federal Government.

(10) *Similar Proposals or Awards*. WARNING—While it is permissible with proposal notification to submit identical proposals or proposals containing a significant amount of Essentially Equivalent Work for consideration under numerous Federal Agency Program Solicitations, it is unlawful to enter into Funding Agreements requiring Essentially Equivalent Work. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award. If an Applicant elects to submit identical proposals or proposals containing a significant amount of Essentially Equivalent Work under other Federal Agency Program Solicitations, a statement must be included in each such proposal indicating:

(i) The name and address of the Federal Agencies to which proposals were submitted or from which awards were received.

(ii) Date of proposal submission or date of award.

(iii) Title, number, and date of Program Solicitations under which proposals were submitted or awards received.

(iv) The specific applicable research topics for each proposal submitted or award received.

(v) Titles of research projects.

(vi) Name and title of Principal Investigator/Project Manager for each proposal submitted or award received.

(11) *Prior SBIR Phase II Awards.* If the SBC has received more than 15 Phase II awards in the prior 5 fiscal years, the SBC must submit in its Phase I proposal: Name of the awarding agency; date of award; Funding Agreement number; amount of award; topic or subtopic title; follow-on agreement amount; source and date of commitment; and current Commercialization status for each Phase II award. (This required proposal information will not be counted toward the proposal pages limitation.)

(f) *Cost Breakdown/Proposed Budget.* The solicitation will require the submission of simplified cost or budget data.

#### § 4. *Method of Selection and Evaluation Criteria.*

(a) *Standard Statement.* Essentially, the following statement must be included in all SBIR or STTR Program Solicitations:

All Phase I and II proposals will be evaluated and judged on a competitive basis. Proposals will be initially screened to determine responsiveness. Proposals passing this initial screening will be technically evaluated by engineers or scientists to determine the most promising technical and scientific approaches. Each proposal will be judged on its own merit. The Federal Agency is under no obligation to fund any proposal or any specific number of proposals in a given topic. It also may elect to fund several or none of the proposed approaches to the same topic or subtopic.

(b) *Evaluation Criteria.*

(1) The SBIR/STTR Participating Agency must develop a standardized method in its evaluation process that will consider, at a minimum, the following factors:

(i) The technical approach and the anticipated agency and commercial benefits that may be derived from the research.

(ii) The adequacy of the proposed effort, and its relationship to the fulfillment of requirements of the research topic or subtopics.

(iii) The soundness and technical merit of the proposed approach and its incremental progress toward topic or subtopic solution.

(iv) Qualifications of the proposed Principal Investigators/Project

Managers, supporting staff, and consultants.

(v) Evaluations of proposals require, among other things, consideration of a proposal's commercial potential as evidenced by:

(A) The SBC's record of commercializing SBIR or other research,

(B) the existence of Phase II funding commitments from private sector or non-SBIR funding sources,

(C) the existence of Phase III follow-on commitments for the subject of the research, and,

(D) the presence of other indicators of the commercial potential of the idea.

(2) The factors in (b)(1) above and other appropriate evaluation criteria, if any, must be specified in the "Method of Selection" section of SBIR Program Solicitations.

(c) *Peer Review.* The Program Solicitation must indicate if the SBIR/STTR Participating Agency contemplates that as a part of the SBIR/STTR proposal evaluation, it will use external peer review.

(d) *Release of Proposal Review Information.* After final award decisions have been announced, the technical evaluations of the Applicant's proposal may be provided to the Applicant. The identity of the reviewer must not be disclosed.

§ 5. *Considerations.* This section must include, as a minimum, the following information:

(a) *Awards.* Indicate the estimated number and type of awards anticipated under the particular SBIR/STTR Program Solicitation in question, including:

(1) Approximate number of Phase I awards expected to be made.

(2) Type of Funding Agreement, that is, contract, grant, or cooperative agreement.

(3) Whether fee or profit will be allowed.

(4) Cost basis of Funding Agreement, for example, fixed-price, cost reimbursement, or cost-plus-fixed fee.

(5) Information on the approximate average dollar value of awards for Phase I and Phase II.

(b) *Reports.* Describe the frequency and nature of reports that will be required under Phase I Funding Agreements. Interim reports should be brief letter reports.

(c) *Payment Schedule.* Specify the method and frequency of progress and final payment under Phase I and II Funding Agreements.

(d) *Innovations, SBIR/STTR Data Rights, Inventions and Patents.*

(1) *Proprietary Information in Proposals.* The following statement must be included in all SBIR/STTR Program Solicitations:

"Information contained in unsuccessful proposals will remain the property of the Applicant. The Federal Government may, however, retain copies of all proposals. Public release of information in any proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information is provided by an Applicant in a proposal, which constitutes a trade secret, commercial or financial information, it will be treated in confidence, to the extent permitted by law, provided that the proposal is clearly marked by the Applicant as follows:

(A) The following legend must appear on the title page of the proposal:

This proposal contains information that shall not be disclosed outside the Federal Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal, unless authorized by law. The Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract if award is made as a result of the submission of this proposal. . . . The information subject to these restrictions are contained on all pages of the proposal except for pages [insert page numbers or other identification of pages that contain no restricted information.]

(End of Legend); and

(B) The following legend must appear on each page of the proposal that contains information the Applicant wishes to protect:

Use or disclosure of information contained on this sheet is subject to the restriction on the title page of this proposal.

(2) *Alternative To Minimize Proprietary Information.* Agencies may elect to instruct Applicants to limit proprietary information to only that absolutely essential to their proposal.

(3) *SBIR/STTR Data Rights Clause.* Participating Agencies must include a clause in their SBIR and STTR Program Solicitations and resulting Funding Agreements that reflects the following necessary elements:

#### *SBIR/STTR Data Rights Clause*

(a) *Definitions.*

(1) *Computer Software.* Computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer Software does not include Computer Databases or Computer Software Documentation.

(2) *Data.* All recorded information, regardless of the form or method of recording or the media on which it may

be recorded. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(3) *Form, Fit, and Function Data.* Data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For Computer Software it means data identifying source, functional characteristics, and performance requirements, but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

(4) *Government Purpose.* Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations or sales or transfers by the United States Government to foreign governments or international organizations. Government Purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Technical Data or Computer Software for commercial purposes or authorize others to do so.

(5) *Operations, Maintenance, Installation, or Training Purposes (OMIT) Data.* Data that is necessary for operation, maintenance, installation, or training purposes (but not including detailed manufacturing or process data).

(6) *SBIR/STTR Computer Software Rights.* The Federal Government's rights during the SBIR/STTR Protection Period in specific types of SBIR/STTR Data that are Computer Software.

(A) The Federal Government may use, modify, reproduce, release, perform, display, or disclose SBIR/STTR Data that are Computer Software within the Government. The Federal Government may exercise SBIR/STTR Computer Software Rights within the Government for:

- (1) Use in Federal Government computers;
- (2) Modification, adaptation, or combination with other Computer Software, provided that the Data incorporated into any derivative software are subject to the rights in § 3(ee) of the SBIR/STTR Policy Directive and that the derivative software is marked as containing SBIR/STTR Data;
- (3) Archive or backup; or
- (4) Distribution of a computer program to another Federal agency, without further permission of the

Awardee, if the Awardee is notified of the distribution and the identity of the recipient prior to the distribution, and a copy of the SBIR/STTR Computer Software Rights included in the Funding Agreement is provided to the recipient.

(B) The Federal Government shall not release, disclose, or permit access to SBIR/STTR Data that is Computer Software for commercial, manufacturing, or procurement purposes without the written permission of the Awardee. The Federal Government shall not release, disclose, or permit access to SBIR/STTR Data outside the Government without the written permission of the Awardee unless:

(i) The non-Governmental entity has entered into a non-disclosure agreement with the Government that complies with the terms for such agreements outlined in § 8 of the SBIR/STTR Policy Directive; and

(ii) The release or disclosure is—  
(I) To a Federal Government support service contractor or their subcontractor for purposes of supporting Government internal use or activities, including evaluation, diagnosis and correction of deficiencies, and adaptation, combination, or integration with other Computer Software provided that SBIR/STTR Data incorporated into any derivative software are subject to the rights in § 3(ee) of the SBIR/STTR Policy Directive; or

(II) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul.

(7) *SBIR/STTR Data.* All Data developed or generated in the performance of an SBIR or STTR award, including Technical Data and Computer Software developed or generated in the performance of an SBIR or STTR award. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(8) *SBIR/STTR Data Rights.* The Federal Government's license rights in properly marked SBIR/STTR Data during the SBIR/STTR Protection Period are as follows: SBIR/STTR Technical Data Rights in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software; and SBIR/STTR Computer Software Rights in SBIR/STTR Data that is Computer Software. Upon expiration of the protection period for SBIR/STTR Data,

the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government Purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties. The Federal Government receives Unlimited Rights in Form Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

(9) *SBIR/STTR Protection Period.* The period of time during which the Federal Government is obligated to protect SBIR/STTR Data against unauthorized use and disclosure in accordance with SBIR/STTR Data Rights. The SBIR/STTR Protection Period begins at award of an SBIR/STTR Funding Agreement and ends not less than twenty years from that date (See § 8(b)(4) of the SBIR/STTR Policy Directive).

(10) *SBIR/STTR Technical Data Rights.* The Federal Government's rights during the SBIR/STTR Protection Period in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software.

(A) The Federal Government may, use, modify, reproduce, perform, display, release, or disclose SBIR/STTR Data that are Technical Data within the Government; however, the Government shall not use, release, or disclose the data for procurement, manufacturing, or commercial purposes; or release or disclose the SBIR/STTR Data outside the Government except as permitted by paragraph (B) below or by written permission of the Awardee.

(B) SBIR/STTR Data that are Technical Data may be released outside the Federal Government without any additional written permission of the Awardee only if the non-Governmental entity or foreign government has entered into a non-disclosure agreement with the Federal Government that complies with the terms for such agreements outlined in § 8 of the SBIR/STTR Policy Directive and the release is:

(i) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul;

(ii) To a Government support services contractor in the performance of a Government support services contract for internal Government use or activities, including evaluation, diagnosis or modification, provided that SBIR/STTR Technical Data incorporated into any derivative Data are subject to the rights in § 3(ii) of the SBIR/STTR Policy Directive, and the release is not

for commercial purposes or manufacture;

(iii) To a foreign government for purposes of information and evaluation if required to serve the interests of the U.S. Government; or

(iv) To non-Government entities or individuals for purposes of evaluation.

(11) *Technical Data*. Recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including Computer Software Documentation and Computer Databases). The term does not include Computer Software or financial, administrative, cost or pricing, or management information, or other data incidental to contract or grant administration. The term includes recorded Data of a scientific or technical nature that is included in Computer Databases.

(12) *Unlimited Rights*. The Government's rights to access, use, modify, prepare derivative works, reproduce, release, perform, display, disclose, or distribute Data in whole or in part, in any manner and for any purpose whatsoever, and to have or authorize others to do so.

(b) *Allocation of SBIR/STTR Data Rights*.

(1) An SBC retains ownership of all SBIR/STTR Data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR Data that are not granted to the Federal Government in accordance with the SBIR/STTR Policy Directive. These rights of the SBC do not expire.

(2) During the SBIR/STTR Protection Period, the Federal Government receives SBIR/STTR Technical Data Rights in appropriately marked SBIR/STTR Data that is Technical Data or any other type of Data other than Computer Software; and SBIR/STTR Computer Software Rights in appropriately marked SBIR/STTR Data that is Computer Software.

(3) After the protection period, the Federal Government may use, and authorize others to use on its behalf, for Government Purposes, SBIR/STTR Data that was protected during the SBIR/STTR Protection Period. Awards issued by the U.S. Department of Energy are subject to Unlimited Rights after the expiration of the SBIR/STTR Protection Period.

(4) The Federal Government receives Unlimited Rights in Form Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data

(c) *Identification and Delivery of SBIR/STTR Data*. Any SBIR/STTR Data delivered by the Awardee, and in which the Awardee intends to limit the Federal Government's rights to SBIR/STTR Data

Rights, must be delivered with restrictive markings. The Federal Government assumes no liability for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR Data without markings. The Awardee or its subcontractors or suppliers shall conspicuously and legibly mark all such SBIR/STTR Data with the appropriate legend.

(1) The authorized legend shall be placed on each page of the SBIR/STTR Data. If only portions of a page are subject to the asserted restrictions, the SBIR/STTR Awardee shall identify the restricted portions (e.g., by circling or underscoring with a note or other appropriate identifier). With respect to SBIR/STTR Data embodied in Computer Software, the legend shall be placed on: (1) The printed material or media containing the Computer Software; or (2) the transmittal document or storage container. The legend shall read as follows:

**SBIR/STTR DATA RIGHTS**

Funding Agreement No .....	
Award Date .....	
SBIR/STTR Protection Period	
SBIR/STTR Awardee .....	
SBIR/STTR Awardee Address	

This is SBIR/STTR Data (or is Computer Software or a Prototype that embodies or includes SBIR/STTR Data) to which the SBIR/STTR Awardee has SBIR/STTR Data Rights and to which the Federal Government has received SBIR/STTR Technical Data Rights (or SBIR/STTR Computer Software Rights) during the SBIR/STTR Protection Period and rights of use for Government Purposes after the SBIR/STTR Protection Period, as those terms are defined in the SBIR/STTR Funding Agreement. Awards issued by the U.S. Department of Energy are subject to Unlimited Rights after the SBIR/STTR Protection Period, as that term is defined in the SBIR/STTR Funding Agreement. Any reproduction of SBIR/STTR Data or portions of such data marked with this legend must also reproduce the markings.

(End of Legend)

(2) Data submitted without correct or appropriate markings may be corrected within 6 months from the date the data is delivered.

(d) *Relation to patents*. Nothing regarding SBIR/STTR Data Rights in this clause shall imply a license to or imply a requirement to license to the Federal Government any patent to a Subject Invention (as defined under the Bayh-

Dole Act implemented at 37 CFR 401) made under an SBIR/STTR award.

(End of Clause)

(4) *Copyrights*. Include an appropriate statement concerning copyrights and publications addressing national security considerations, if any, and the appropriate acknowledgement and disclaimer statement.

(5) *Invention Reporting*. Include requirements for reporting inventions. Include appropriate information concerning the reporting of inventions, for example:

SBIR/STTR Awardees must report inventions to the awarding agency within 2 months of the inventor's report to the Awardee.

**Note:** Many federal agencies require electronic reporting of inventions and patents made with Federal funds through the Interagency Invention Reporting System (iEdison) that is maintained and managed by NIH. The iEdison System is used to satisfy all invention reporting requirements mandated by an SBIR/STTR award. Access to iEdison is through a secure interactive internet site, <http://www.iedison.gov>. All Federal Agencies are encouraged to use the iEdison System. In addition to fulfilling reporting requirements, iEdison notifies the user of future time sensitive deadlines with enough lead-time to avoid the possibility of loss of invention or patent ownership or rights.

(e) *Cost Sharing*. Include a statement essentially as follows:

Cost sharing is permitted for proposals under this Program Solicitation; however, cost sharing is not required. Cost sharing will not be an evaluation factor in consideration of your Phase I proposal.

(f) *Profit or Fee*. Include a statement on the payment of profit or fee on awards made under the SBIR/STTR Program Solicitation.

(g) *Joint Ventures or Limited Partnerships*. Include essentially the following language:

Joint Ventures and limited partnerships are eligible provided the entity created qualifies as a Small Business Concern as defined in this Program Solicitation.

(h) *Research and Analytical Work*. Include essentially the following statement:

SBIR:

(1) For Phase I a minimum of two-thirds of the research and/or analytical effort must be performed by the proposing Small Business Concern unless otherwise approved in writing by the Funding Agreement officer after consultation with the agency SBIR program manager/coordinator.

(2) For Phase II a minimum of one-half of the research and/or analytical effort must be performed by the proposing Small Business Concern unless otherwise approved in writing by the Funding Agreement officer

after consultation with the agency SBIR program manager/coordinator.

**STTR:**

For both Phase I and Phase II, not less than 40 percent of the R/R&D work must be performed by the Small Business Concern, and not less than 30 percent of the R/R&D work must be performed by a partnering Research Institution, as defined in this Program Solicitation.

(i) *Awardee Commitments.* To meet the legislative requirement that SBIR/STTR Program Solicitations be simplified, standardized and uniform, clauses expected to be in or required to be included in SBIR/STTR Funding Agreements must not be included in full or by reference in SBIR/STTR Program Solicitations. Rather, Applicants must be advised that they will be required to make certain legal commitments at the time of execution of Funding Agreements resulting from SBIR/STTR Program Solicitations. Essentially, the following statement must be included in the "Considerations" section of SBIR/STTR Program Solicitations:

Upon award of a Funding Agreement, the Awardee will be required to make certain legal commitments through acceptance of numerous clauses in Phase I Funding Agreements. The outline that follows is illustrative of the types of clauses to which the contractor would be committed. This list is not a complete list of clauses to be included in Phase I Funding Agreements, and is not the specific wording of such clauses. Copies of complete terms and conditions are available upon request.

(j) *Summary Statements.* The following are illustrative of the type of summary statements to be included immediately following the statement in subparagraph (i). These statements are examples only and may vary depending upon the type of Funding Agreement used.

(1) *Standards of Work.* Work performed under the Funding Agreement must conform to high professional standards.

(2) *Inspection.* Work performed under the Funding Agreement is subject to Government inspection and evaluation at all times.

(3) *Examination of Records.* The Comptroller General (or a duly authorized representative) must have the right to examine any pertinent records of the Awardee involving transactions related to this Funding Agreement.

(4) *Default.* The Federal Government may terminate the Funding Agreement if the contractor fails to perform the work contracted.

(5) *Termination for Convenience.* The Funding Agreement may be terminated at any time by the Federal Government

if it deems termination to be in its best interest, in which case the Awardee will be compensated for work performed and for reasonable termination costs.

(6) *Disputes.* Any dispute concerning the Funding Agreement that cannot be resolved by agreement must be decided by the contracting officer with right of appeal.

(7) *Contract Work Hours.* The Awardee may not require an employee to work more than 8 hours a day or 40 hours a week unless the employee is compensated accordingly (for example, overtime pay).

(8) *Equal Opportunity.* The Awardee will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

(9) *Equal Opportunity for Veterans.* The Awardee will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era.

(10) *Equal Opportunity for People with Disabilities.* The Awardee will not discriminate against any employee or applicant for employment because he or she is physically or intellectually disabled.

(11) *Officials Not To Benefit.* No Federal Government official may benefit personally from the SBIR/STTR Funding Agreement.

(12) *Covenant Against Contingent Fees.* No person or agency has been employed to solicit or secure the Funding Agreement upon an understanding for compensation except bona fide employees or commercial agencies maintained by the Awardee for the purpose of securing business.

(13) *Gratuities.* The Funding Agreement may be terminated by the Federal Government if any gratuities have been offered to any representative of the Government to secure the award.

(14) *Patent Infringement.* The Awardee must report each notice or claim of patent infringement based on the performance of the Funding Agreement.

(15) *American Made Equipment and Products.* When purchasing equipment or a product under the SBIR/STTR Funding Agreement, purchase only American-made items whenever possible.

(k) *Additional Information.* Information pertinent to an understanding of the administration requirements of SBIR/STTR proposals and Funding Agreements not included elsewhere must be included in this section. As a minimum, statements essentially as follows must be included

under "Additional Information" in SBIR/STTR Program Solicitations:

(1) This Program Solicitation is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR/STTR Funding Agreement, the terms of the Funding Agreement are controlling.

(2) Before award of an SBIR/STTR Funding Agreement, the Federal Government may request the Applicant to submit certain organizational, management, personnel, and financial information to assure responsibility of the Applicant.

(3) The Federal Government is not responsible for any monies expended by the Applicant before award of any Funding Agreement.

(4) This Program Solicitation is not an offer by the Federal Government and does not obligate the Government to make any specific number of awards. Also, awards under the SBIR/STTR program are contingent upon the availability of funds.

(5) The SBIR/STTR program is not a substitute for existing unsolicited proposal mechanisms. Unsolicited proposals must not be accepted under the SBIR/STTR program in either Phase I or Phase II.

(6) If an award is made pursuant to a proposal submitted under this SBIR/STTR Program Solicitation, a representative of the contractor or grantee or party to a cooperative agreement will be required to certify that the concern has not previously been, nor is currently being, paid for Essentially Equivalent Work by any Federal Agency.

**§ 6. Submission of Proposals.**

(a) This section must clearly specify the closing date on which all proposals are due to be received.

(b) This section must specify the number of copies of the proposal that are to be submitted.

(c) This section must clearly set forth the complete mailing and/or delivery address(es) where proposals are to be submitted.

(d) This section may include other instructions such as the following:

(1) *Bindings.* Please do not use special bindings or covers. Staple the pages in the upper left corner of the cover sheet of each proposal.

(2) *Packaging.* All copies of a proposal should be sent in the same package.

**§ 7. Scientific and Technical Information Sources.** Wherever descriptions of research topics or subtopics include reference to publications, information on where such publications will normally be

available must be included in a separate section of the solicitation entitled "Scientific and Technical Information Sources."

§ 8. *Submission Forms*. Multiple copies of proposal preparation forms necessary to the contracting and granting process may be required. This section may include Proposal Summary,

Proposal Cover, Budget, Checklist, and other forms the sole purpose of which is to meet the mandate of law or regulation and simplify the submission of proposals.

§ 9. *Research Topics*. Describe sufficiently the R/R&D topics and subtopics for which proposals are being solicited to inform the Applicant of

technical details of what is desired. Allow flexibility in order to obtain the greatest degree of creativity and innovation consistent with the overall objectives of the SBIR/STTR program.

[FR Doc. 2019-06129 Filed 4-1-19; 8:45 am]

**BILLING CODE 8025-01-P**



# FEDERAL REGISTER

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Part V

## The President

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Executive Order 13866—Adjustments of Certain Rates of Pay  
Memorandum of March 28, 2019—Extension of Deferred Enforced  
Departure for Liberians



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# Presidential Documents

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**Title 3—****Executive Order 13866 of March 28, 2019****The President****Adjustments of Certain Rates of Pay**

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

**Section 1. *Statutory Pay Systems.*** The rates of basic pay or salaries of the statutory pay systems (as defined in 5 U.S.C. 5302(1)), as adjusted under 5 U.S.C. 5303 and section 748 of title VII of division D of the Consolidated Appropriations Act, 2019 (Public Law 116–6), are set forth on the schedules attached hereto and made a part hereof:

- (a) The General Schedule (5 U.S.C. 5332(a)) at Schedule 1;
- (b) The Foreign Service Schedule (22 U.S.C. 3963) at Schedule 2; and
- (c) The schedules for the Veterans Health Administration of the Department of Veterans Affairs (38 U.S.C. 7306, 7404; section 301(a) of Public Law 102–40) at Schedule 3.

**Sec. 2. *Senior Executive Service.*** The ranges of rates of basic pay for senior executives in the Senior Executive Service, as established pursuant to 5 U.S.C. 5382, are set forth on Schedule 4 attached hereto and made a part hereof.

**Sec. 3. *Certain Executive, Legislative, and Judicial Salaries.*** The rates of basic pay or salaries for the following offices and positions are set forth on the schedules attached hereto and made a part hereof:

- (a) The Executive Schedule (5 U.S.C. 5312–5318) at Schedule 5;
- (b) The Vice President (3 U.S.C. 104) and the Congress (2 U.S.C. 4501) at Schedule 6; and
- (c) Justices and judges (28 U.S.C. 5, 44(d), 135, 252, and 461(a)) at Schedule 7.

**Sec. 4. *Uniformed Services.*** The rates of monthly basic pay (37 U.S.C. 203(a)) for members of the uniformed services, as adjusted under 37 U.S.C. 1009, and the rate of monthly cadet or midshipman pay (37 U.S.C. 203(c)) are set forth on Schedule 8 attached hereto and made a part hereof.

**Sec. 5. *Locality-Based Comparability Payments.***

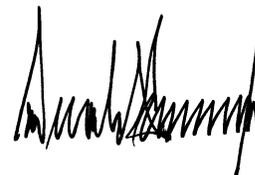
(a) Pursuant to sections 5304 and 5304a of title 5, United States Code, and section 748 of title VII of division D of the Consolidated Appropriations Act, 2019 (Public Law 116–6), locality-based comparability payments shall be paid in accordance with Schedule 9 attached hereto and made a part hereof.

(b) The Director of the Office of Personnel Management shall take such actions as may be necessary to implement these payments and to publish appropriate notice of such payments in the *Federal Register*.

**Sec. 6. *Administrative Law Judges.*** Pursuant to section 5372 of title 5, United States Code, the rates of basic pay for administrative law judges are set forth on Schedule 10 attached hereto and made a part hereof.

**Sec. 7. *Effective Dates.*** Schedule 8 is effective January 1, 2019. The other schedules contained herein are effective on the first day of the first applicable pay period beginning on or after January 1, 2019.

**Sec. 8. *Prior Order Superseded.*** Executive Order 13856 of December 28, 2018, is superseded as of the effective dates specified in section 7 of this order.



THE WHITE HOUSE,  
March 28, 2019.

**SCHEDULE 1--GENERAL SCHEDULE**

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2019)

	1	2	3	4	5	6	7	8	9	10
GS-1	\$19,048	\$19,686	\$20,320	\$20,949	\$21,583	\$21,953	\$22,579	\$23,211	\$23,236	\$23,827
GS-2	21,417	21,927	22,636	23,236	23,497	24,188	24,879	25,570	26,261	26,952
GS-3	23,368	24,147	24,926	25,705	26,484	27,263	28,042	28,821	29,600	30,379
GS-4	26,233	27,107	27,981	28,855	29,729	30,603	31,477	32,351	33,225	34,099
GS-5	29,350	30,328	31,306	32,284	33,262	34,240	35,218	36,196	37,174	38,152
GS-6	32,716	33,807	34,898	35,989	37,080	38,171	39,262	40,353	41,444	42,535
GS-7	36,356	37,568	38,780	39,992	41,204	42,416	43,628	44,840	46,052	47,264
GS-8	40,263	41,605	42,947	44,289	45,631	46,973	48,315	49,657	50,999	52,341
GS-9	44,471	45,953	47,435	48,917	50,399	51,881	53,363	54,845	56,327	57,809
GS-10	48,973	50,605	52,237	53,869	55,501	57,133	58,765	60,397	62,029	63,661
GS-11	53,805	55,599	57,393	59,187	60,981	62,775	64,569	66,363	68,157	69,951
GS-12	64,490	66,640	68,790	70,940	73,090	75,240	77,390	79,540	81,690	83,840
GS-13	76,687	79,243	81,799	84,355	86,911	89,467	92,023	94,579	97,135	99,691
GS-14	90,621	93,642	96,663	99,684	102,705	105,726	108,747	111,768	114,789	117,810
GS-15	106,595	110,148	113,701	117,254	120,807	124,360	127,913	131,466	135,019	138,572

**SCHEDULE 2--FOREIGN SERVICE SCHEDULE**

(Effective on the first day of the first applicable pay period beginning on or after January 1, 2019)

Step	Class 1	Class 2	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8	Class 9
1	\$106,595	\$86,374	\$69,988	\$56,711	\$45,953	\$41,081	\$36,725	\$32,831	\$29,350
2	109,793	88,965	72,088	58,412	47,332	42,313	37,827	33,816	30,231
3	113,087	91,634	74,250	60,165	48,752	43,583	38,962	34,830	31,137
4	116,479	94,383	76,478	61,970	50,214	44,890	40,130	35,875	32,072
5	119,974	97,215	78,772	63,829	51,721	46,237	41,334	36,952	33,034
6	123,573	100,131	81,135	65,744	53,272	47,624	42,574	38,060	34,025
7	127,280	103,135	83,569	67,716	54,870	49,053	43,852	39,202	35,045
8	131,098	106,229	86,076	69,747	56,516	50,524	45,167	40,378	36,097
9	135,031	109,416	88,659	71,840	58,212	52,040	46,522	41,589	37,180
10	138,572	112,698	91,318	73,995	59,958	53,601	47,918	42,837	38,295
11	138,572	116,079	94,058	76,215	61,757	55,209	49,355	44,122	39,444
12	138,572	119,562	96,880	78,501	63,610	56,866	50,836	45,446	40,627
13	138,572	123,149	99,786	80,856	65,518	58,572	52,361	46,809	41,846
14	138,572	126,843	102,780	83,282	67,484	60,329	53,932	48,213	43,101

**SCHEDULE 3--VETERANS HEALTH ADMINISTRATION SCHEDULES  
DEPARTMENT OF VETERANS AFFAIRS**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

Schedule for the Office of the Under Secretary for Health  
(38 U.S.C. 7306)\*

<u>Minimum</u>	<u>Maximum</u>
\$127,914	\$156,000**

Physician, Dentist, and Podiatrist Base and Longevity Schedule\*\*\*

Physician Grade . . . . .	\$104,843	\$153,773
Dentist Grade . . . . .	104,843	153,773
Podiatrist Grade . . . . .	104,843	153,773

Chiropractor and Optometrist Schedule

Chief Grade . . . . .	\$106,595	\$138,572
Senior Grade. . . . .	90,621	117,810
Intermediate Grade. . . . .	76,687	99,691
Full Grade. . . . .	64,490	83,840
Associate Grade . . . . .	53,805	69,951

Physician Assistant and Expanded-Function  
Dental Auxiliary Schedule\*\*\*\*

Director Grade. . . . .	\$106,595	\$138,572
Assistant Director Grade. . . . .	90,621	117,810
Chief Grade . . . . .	76,687	99,691
Senior Grade. . . . .	64,490	83,840
Intermediate Grade. . . . .	53,805	69,951
Full Grade. . . . .	44,471	57,809
Associate Grade . . . . .	38,268	49,752
Junior Grade. . . . .	32,716	42,535

\* This schedule does not apply to the Director of Nursing Service or any incumbents who are physicians or dentists.

\*\* Pursuant to 38 U.S.C. 7404(d), the rate of basic pay payable to these employees is limited to the rate for level V of the Executive Schedule, which is \$156,000.

\*\*\* Pursuant to section 3 of Public Law 108-445 and 38 U.S.C. 7431, Veterans Health Administration physicians and dentists may also be paid market pay and performance pay.

\*\*\*\* Pursuant to section 301(a) of Public Law 102-40, these positions are paid according to the Nurse Schedule in 38 U.S.C. 4107(b), as in effect on August 14, 1990, with subsequent adjustments.

**SCHEDULE 4--SENIOR EXECUTIVE SERVICE**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

	<u>Minimum</u>	<u>Maximum</u>
Agencies with a Certified SES		
Performance Appraisal System . . . . .	\$127,914	\$192,300
Agencies without a Certified SES		
Performance Appraisal System . . . . .	\$127,914	\$176,900

**SCHEDULE 5--EXECUTIVE SCHEDULE**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

Level I . . . . .	\$213,600
Level II . . . . .	192,300
Level III. . . . .	176,900
Level IV . . . . .	166,500
Level V . . . . .	156,000

**SCHEDULE 6--VICE PRESIDENT AND MEMBERS OF CONGRESS**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

Vice President . . . . .	\$246,900
Senators . . . . .	174,000
Members of the House of Representatives. . . . .	174,000
Delegates to the House of Representatives. . . . .	174,000
Resident Commissioner from Puerto Rico . . . . .	174,000
President pro tempore of the Senate. . . . .	193,400
Majority leader and minority leader of the Senate. . . . .	193,400
Majority leader and minority leader of the House of Representatives . . . . .	193,400
Speaker of the House of Representatives. . . . .	223,500

**SCHEDULE 7--JUDICIAL SALARIES**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

Chief Justice of the United States . . . . .	\$270,700
Associate Justices of the Supreme Court. . . . .	258,900
Circuit Judges . . . . .	223,700
District Judges. . . . .	210,900
Judges of the Court of International Trade . . . . .	210,900

**SCHEDULE 8--PAY OF THE UNIFORMED SERVICES  
(Effective January 1, 2019)**

**Part I--MONTHLY BASIC PAY  
YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)**

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18
<b>COMMISSIONED OFFICERS</b>											
O-10*	-	-	-	-	-	-	-	-	-	-	-
O-9	-	-	-	-	-	-	-	-	-	-	-
O-8	\$10,668.90	\$11,018.70	\$11,250.60	\$11,315.40	\$11,604.90	\$12,088.20	\$12,200.70	\$12,659.70	\$12,791.70	\$13,187.10	\$13,759.50
O-7	8,865.30	9,276.90	9,467.70	9,619.20	9,893.40	10,164.60	10,477.80	10,790.10	11,103.60	12,088.20	12,919.20
O-6**	6,722.70	7,385.70	7,870.50	7,870.50	7,900.50	8,239.20	8,283.90	8,283.90	8,754.30	9,586.80	10,075.20
O-5	5,604.30	6,313.50	6,750.00	6,832.50	7,105.50	7,268.40	7,627.20	7,890.90	8,230.80	8,751.30	8,998.50
O-4	4,835.40	5,597.40	5,971.20	6,054.00	6,400.80	6,772.80	7,236.00	7,596.30	7,846.50	7,990.50	8,073.90
O-3***	4,251.60	4,819.20	5,201.40	5,671.50	5,943.60	6,241.50	6,434.40	6,751.20	6,916.80	6,916.80	6,916.80
O-2***	3,673.50	4,183.80	4,818.30	4,981.20	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80
O-1***	3,188.40	3,318.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90
<b>COMMISSIONED OFFICERS WITH OVER 4 YEARS ACTIVE DUTY SERVICE AS AN ENLISTED MEMBER OR WARRANT OFFICER****</b>											
O-3E	-	-	-	\$5,671.50	\$5,943.60	\$6,241.50	\$6,434.40	\$6,751.20	\$7,018.80	\$7,172.70	\$7,381.80
O-2E	-	-	-	4,981.20	5,083.80	5,245.50	5,518.80	5,730.00	5,887.20	5,887.20	5,887.20
O-1E	-	-	-	4,011.90	4,284.00	4,442.40	4,604.40	4,763.40	4,981.20	4,981.20	4,981.20
<b>WARRANT OFFICERS</b>											
W-5	-	-	-	-	-	-	-	-	-	-	-
W-4	\$4,393.80	\$4,726.20	\$4,861.80	\$4,995.30	\$5,225.10	\$5,452.80	\$5,683.20	\$6,029.10	\$6,333.00	\$6,621.90	\$6,858.60
W-3	4,012.50	4,179.60	4,351.20	4,407.60	4,586.70	4,940.40	5,308.50	5,482.20	5,682.90	5,889.00	6,261.00
W-2	3,550.50	3,886.20	3,989.70	4,060.50	4,290.90	4,648.80	4,826.10	5,000.40	5,214.00	5,381.10	5,532.00
W-1	3,116.40	3,452.10	3,542.10	3,732.60	3,957.90	4,290.30	4,445.10	4,662.00	4,875.30	5,043.30	5,197.50

\* Basic pay is limited to the rate of basic pay for level II of the Executive Schedule in effect during calendar year 2019, which is \$16,025.10 per month for officers at pay grades O-7 through O-10. This includes officers serving as Chairman or Vice Chairman of the Joint Chiefs of Staff, Chief of Staff of the Army, Chief of Naval Operations, Chief of Staff of the Air Force, Commandant of the Marine Corps, Commandant of the Coast Guard, Chief of the National Guard Bureau, or commander of a unified or specified combatant command (as defined in 10 U.S.C. 161(c)).

\*\* Basic pay is limited to the rate of basic pay for level V of the Executive Schedule in effect during calendar year 2019, which is \$12,999.90 per month, for officers at pay grades O-6 and below.

\*\*\* Does not apply to commissioned officers who have been credited with over 4 years of active duty service as an enlisted member or warrant officer.

\*\*\*\* Reservists with at least 1,460 points as an enlisted member, a warrant officer, or a warrant officer and an enlisted member which are creditable toward reserve retirement also qualify for these rates.

**SCHEDULE 8--PAY OF THE UNIFORMED SERVICES (PAGE 2)**  
(Effective January 1, 2019)

Pay Grade	Part I--MONTHLY BASIC PAY										
	YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)										
	Over 20	Over 22	Over 24	Over 26	Over 28	Over 30	Over 32	Over 34	Over 36	Over 38	Over 40
	<b>COMMISSIONED OFFICERS</b>										
O-10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*	\$16,025.10*
O-9	15,078.60	15,296.40	15,610.20	16,025.10*	16,025.10*	16,025.10*	16,025.10*	16,025.10*	16,025.10*	16,025.10*	16,025.10*
O-8	14,287.20	14,639.40	14,639.40	14,639.40	14,639.40	15,006.00	15,006.00	15,380.70	15,380.70	15,380.70	15,380.70
O-7	12,919.20	12,919.20	12,919.20	12,985.50	12,985.50	13,245.30	13,245.30	13,245.30	13,245.30	13,245.30	13,245.30
O-6**	10,563.30	10,841.40	11,123.10	11,668.20	11,668.20	11,901.30	11,901.30	11,901.30	11,901.30	11,901.30	11,901.30
O-5	9,243.60	9,521.40	9,521.40	9,521.40	9,521.40	9,521.40	9,521.40	9,521.40	9,521.40	9,521.40	9,521.40
O-4	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90	8,073.90
O-3***	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80	6,916.80
O-2***	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80	5,083.80
O-1***	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90	4,011.90
	<b>COMMISSIONED OFFICERS WITH OVER 4 YEARS ACTIVE DUTY SERVICE AS AN ENLISTED MEMBER OR WARRANT OFFICER****</b>										
O-3E	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80	\$7,381.80
O-2E	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20	5,887.20
O-1E	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20	4,981.20
	<b>WARRANT OFFICERS</b>										
W-5	\$7,812.60	\$8,208.60	\$8,503.80	\$8,830.50	\$8,830.50	\$9,272.70	\$9,272.70	\$9,735.60	\$9,735.60	\$10,223.40	\$10,223.40
W-4	7,089.30	7,428.00	7,706.40	8,024.10	8,024.10	8,184.00	8,184.00	8,184.00	8,184.00	8,184.00	8,184.00
W-3	6,511.80	6,661.80	6,821.10	7,038.60	7,038.60	7,038.60	7,038.60	7,038.60	7,038.60	7,038.60	7,038.60
W-2	5,713.20	5,832.00	5,926.20	5,926.20	5,926.20	5,926.20	5,926.20	5,926.20	5,926.20	5,926.20	5,926.20
W-1	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30	5,385.30

\* Basic pay is limited to the rate of basic pay for level II of the Executive Schedule in effect during calendar year 2019, which is \$16,025.10 per month for officers at pay grades O-7 through O-10. This includes officers serving as Chairman or Vice Chairman of the Joint Chiefs of Staff, Chief of Staff of the Army, Chief of Naval Operations, Chief of Staff of the Air Force, Commandant of the Marine Corps, Commandant of the Coast Guard, Chief of the National Guard Bureau, or commander of a unified or specified combatant command (as defined in 10 U.S.C. 161(c)).

\*\* Basic pay is limited to the rate of basic pay for level V of the Executive Schedule in effect during calendar year 2019, which is \$12,999.90 per month, for officers at pay grades O-6 and below.

\*\*\* Does not apply to commissioned officers who have been credited with over 4 years of active duty service as an enlisted member or warrant officer.

\*\*\*\* Reservists with at least 1,460 points as an enlisted member, a warrant officer, or a warrant officer and an enlisted member which are creditable toward reserve retirement also qualify for these rates.

SCHEDULE 8--PAY OF THE UNIFORMED SERVICES (PAGE 3)  
(Effective January 1, 2019)

Part I--MONTHLY BASIC PAY

YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18
ENLISTED MEMBERS											
E-9*	-	-	-	-	-	-	\$5,308.20	\$5,428.50	\$5,580.30	\$5,758.20	\$5,938.80
E-8	-	-	-	-	-	\$4,345.50	4,537.50	4,656.60	4,798.80	4,953.60	5,232.30
E-7	\$3,020.70	\$3,296.70	\$3,423.30	\$3,590.10	\$3,720.90	3,945.00	4,071.60	4,295.70	4,482.60	4,609.80	4,745.40
E-6	2,612.70	2,875.20	3,002.10	3,125.40	3,254.10	3,543.30	3,656.40	3,874.80	3,941.40	3,990.00	4,046.70
E-5	2,393.40	2,554.80	2,678.10	2,804.40	3,001.50	3,207.00	3,376.20	3,396.60	3,396.60	3,396.60	3,396.60
E-4	2,194.50	2,307.00	2,431.80	2,555.40	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00
E-3	1,981.20	2,105.70	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50
E-2	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00
E-1**	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90
E-1***	1,554.00	-	-	-	-	-	-	-	-	-	-

\* For noncommissioned officers serving as Sergeant Major of the Army, Master Chief Petty Officer of the Navy or Coast Guard, Chief Master Sergeant of the Air Force, Sergeant Major of the Marine Corps, Senior Enlisted Advisor to the Chairman of the Joint Chiefs of Staff, or Senior Enlisted Advisor to the Chief of the National Guard Bureau, basic pay for this grade is \$8,578.50 per month, regardless of cumulative years of service under 37 U.S.C. 205.

\*\* Applies to personnel who have served 4 months or more on active duty.

\*\*\* Applies to personnel who have served less than 4 months on active duty.

**SCHEDULE 8--PAY OF THE UNIFORMED SERVICES (PAGE 4)**  
 (Effective January 1, 2019)

**Part I--MONTHLY BASIC PAY**

**YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)**

Pay Grade	Over 20	Over 22	Over 24	Over 26	Over 28	Over 30	Over 32	Over 34	Over 36	Over 38	Over 40
	<b>ENLISTED MEMBERS</b>										
E-9*	\$6,226.50	\$6,470.70	\$6,726.60	\$7,119.30	\$7,119.30	\$7,474.80	\$7,474.80	\$7,848.90	\$7,848.90	\$8,241.90	\$8,241.90
E-8	5,373.60	5,613.90	5,747.40	6,075.60	6,075.60	6,197.70	6,197.70	6,197.70	6,197.70	6,197.70	6,197.70
E-7	4,797.60	4,974.30	5,068.80	5,429.10	5,429.10	5,429.10	5,429.10	5,429.10	5,429.10	5,429.10	5,429.10
E-6	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70	4,046.70
E-5	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60	3,396.60
E-4	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00	2,664.00
E-3	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50	2,233.50
E-2	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00	1,884.00
E-1**	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90
E-1***	-	-	-	-	-	-	-	-	-	-	-

\* For noncommissioned officers serving as Sergeant Major of the Army, Master Chief Petty Officer of the Navy or Coast Guard, Chief Master Sergeant of the Air Force, Sergeant Major of the Marine Corps, Senior Enlisted Advisor to the Chairman of the Joint Chiefs of Staff, or Senior Enlisted Advisor to the Chief of the National Guard Bureau, basic pay for this grade is \$8,578.50 per month, regardless of cumulative years of service under 37 U.S.C. 205.

\*\* Applies to personnel who have served 4 months or more on active duty.

\*\*\* Applies to personnel who have served less than 4 months on active duty.

## SCHEDULE 8--PAY OF THE UNIFORMED SERVICES (PAGE 5)

## Part II--RATE OF MONTHLY CADET OR MIDSHIPMAN PAY

The rate of monthly cadet or midshipman pay authorized by 37 U.S.C. 203(c) is \$1,116.00.

Note: As a result of the enactment of sections 602-604 of Public Law 105-85, the National Defense Authorization Act for Fiscal Year 1998, the Secretary of Defense now has the authority to adjust the rates of basic allowances for subsistence and housing. Therefore, these allowances are no longer adjusted by the President in conjunction with the adjustment of basic pay for members of the uniformed services. Accordingly, the tables of allowances included in previous orders are not included here.

**SCHEDULE 9--LOCALITY-BASED COMPARABILITY PAYMENTS**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

<u>Locality Pay Area*</u>	<u>Rate</u>
Alaska .....	28.89%
Albany-Schenectady, NY-MA .....	17.19%
Albuquerque-Santa Fe-Las Vegas, NM .....	16.20%
Atlanta-Athens-Clarke County-Sandy Springs, GA-AL .....	21.64%
Austin-Round Rock, TX .....	17.46%
Birmingham-Hoover-Talladega, AL .....	15.77%
Boston-Worcester-Providence, MA-RI-NH-ME .....	28.27%
Buffalo-Cheektowaga, NY .....	19.67%
Burlington-South Burlington, VT .....	16.18%
Charlotte-Concord, NC-SC .....	16.79%
Chicago-Naperville, IL-IN-WI .....	28.05%
Cincinnati-Wilmington-Maysville, OH-KY-IN .....	20.21%
Cleveland-Akron-Canton, OH .....	20.45%
Colorado Springs, CO .....	17.19%
Columbus-Marion-Zanesville, OH .....	19.47%
Corpus Christi-Kingsville-Alice, TX .....	16.01%
Dallas-Fort Worth, TX-OK .....	24.21%
Davenport-Moline, IA-IL .....	16.49%
Dayton-Springfield-Sidney, OH .....	18.61%
Denver-Aurora, CO .....	26.30%
Detroit-Warren-Ann Arbor, MI .....	26.81%
Harrisburg-Lebanon, PA .....	16.65%
Hartford-West Hartford, CT-MA .....	28.87%
Hawaii .....	18.98%
Houston-The Woodlands, TX .....	32.54%
Huntsville-Decatur-Albertville, AL .....	19.18%
Indianapolis-Carmel-Muncie, IN .....	16.57%
Kansas City-Overland Park-Kansas City, MO-KS .....	16.60%
Laredo, TX .....	18.22%
Las Vegas-Henderson, NV-AZ .....	17.04%
Los Angeles-Long Beach, CA .....	31.47%
Miami-Fort Lauderdale-Port St. Lucie, FL .....	23.12%
Milwaukee-Racine-Waukesha, WI .....	20.58%
Minneapolis-St. Paul, MN-WI .....	24.00%
New York-Newark, NY-NJ-CT-PA .....	33.06%
Omaha-Council Bluffs-Fremont, NE-IA .....	15.87%
Palm Bay-Melbourne-Titusville, FL .....	16.33%
Philadelphia-Reading-Camden, PA-NJ-DE-MD .....	25.30%
Phoenix-Mesa-Scottsdale, AZ .....	19.60%
Pittsburgh-New Castle-Weirton, PA-OH-WV .....	18.86%
Portland-Vancouver-Salem, OR-WA .....	23.13%
Raleigh-Durham-Chapel Hill, NC .....	19.99%
Richmond, VA .....	19.38%
Sacramento-Roseville, CA-NV .....	25.59%
San Antonio-New Braunfels-Pearsall, TX .....	16.07%
San Diego-Carlsbad, CA .....	28.80%
San Jose-San Francisco-Oakland, CA .....	40.35%
Seattle-Tacoma, WA .....	26.04%
St. Louis-St. Charles-Farmington, MO-IL .....	17.05%
Tucson-Nogales, AZ .....	16.68%
Virginia Beach-Norfolk, VA-NC .....	15.91%
Washington-Baltimore-Arlington, DC-MD-VA-WV-PA .....	29.32%
Rest of U.S. ....	15.67%

\* Locality Pay Areas are defined in 5 CFR 531.603.

**SCHEDULE 10--ADMINISTRATIVE LAW JUDGES**

(Effective on the first day of the first applicable pay period  
beginning on or after January 1, 2019)

AL-3/A .....	\$111,100
AL-3/B .....	119,600
AL-3/C .....	128,200
AL-3/D .....	136,800
AL-3/E .....	145,500
AL-3/F .....	153,800
AL-2 .....	162,300
AL-1 .....	166,500

## Presidential Documents

**Memorandum of March 28, 2019**

### **Extension of Deferred Enforced Departure for Liberians**

#### **Memorandum for the Secretary of State [and] the Secretary of Homeland Security**

Since March 1991, certain Liberian nationals and persons without nationality who last habitually resided in Liberia (collectively, “Liberians”) have been eligible for either Temporary Protected Status (TPS) or Deferred Enforced Departure (DED), allowing them to remain in the United States despite being otherwise removable.

In a memorandum dated March 27, 2018, I determined that, although conditions in Liberia had improved and did not warrant a further extension of DED, the foreign policy interests of the United States warranted affording an orderly transition (“wind-down”) period to Liberian DED beneficiaries. At that time, I determined that a 12-month wind-down period was appropriate; that wind-down period expires on March 31, 2019.

Upon further reflection and review, I have decided that it is in the foreign policy interest of the United States to extend the wind-down period for an additional 12 months, through March 30, 2020. The overall situation in West Africa remains concerning, and Liberia is an important regional partner for the United States. The reintegration of DED beneficiaries into Liberian civil and political life will be a complex task, and an unsuccessful transition could strain United States-Liberian relations and undermine Liberia’s post-civil war strides toward democracy and political stability. Further, I understand that there are efforts underway by Members of Congress to provide relief for the small population of Liberian DED beneficiaries who remain in the United States. Extending the wind-down period will preserve the status quo while the Congress considers remedial legislation.

The relationship between the United States and Liberia is unique. Former African-American slaves were among those who founded the modern state of Liberia in 1847. Since that time, the United States has sought to honor, through a strong bilateral diplomatic partnership, the sacrifices of individuals who were determined to build a modern democracy in Africa with representative political institutions similar to those of the United States.

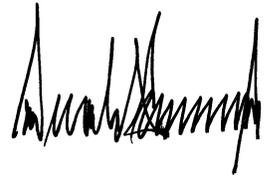
Pursuant to my constitutional authority to conduct the foreign relations of the United States, I hereby direct the Secretary of Homeland Security to take appropriate measures to accomplish the following:

- (1) The termination of DED for all Liberian beneficiaries effective March 31, 2020;
- (2) A continuation of the wind-down period through March 30, 2020, during which current Liberian DED beneficiaries who satisfy the description below may remain in the United States; and
- (3) As part of that wind-down, continued authorization for employment through March 30, 2020, for current Liberian DED beneficiaries who satisfy the description below.

The 12-month wind-down period and 12-month continued authorization for employment shall apply to any current Liberian DED beneficiary who has continuously resided in the United States since October 1, 2002, but shall not apply to Liberians in the following categories:

- (1) Individuals who are ineligible for TPS for reasons set forth in section 244(c)(2)(B) of the Immigration and Nationality Act (8 U.S.C. 1254a(c)(2)(B));
- (2) Individuals whose removal the Secretary of Homeland Security determines to be in the interest of the United States;
- (3) Individuals whose presence or activities in the United States the Secretary of State has reasonable grounds to believe would have potentially serious adverse foreign policy consequences for the United States;
- (4) Individuals who have voluntarily returned to Liberia or their country of last habitual residence outside the United States;
- (5) Individuals who were deported, excluded, or removed before the date of this memorandum; or
- (6) Individuals who are subject to extradition.

The Secretary of Homeland Security is authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be the signature of the Secretary of Homeland Security, located on the right side of the page.

THE WHITE HOUSE,  
Washington, March 28, 2019



# FEDERAL REGISTER

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Vol. 84

Tuesday,

No. 63

April 2, 2019

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Part VI

The President

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Notice of April 1, 2019—Continuation of the National Emergency With Respect to South Sudan



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**Presidential Documents**

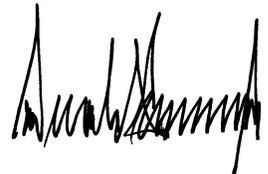
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**Title 3—****Notice of April 1, 2019****The President****Continuation of the National Emergency With Respect to South Sudan**

On April 3, 2014, by Executive Order 13664, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the situation in and in relation to South Sudan, which has been marked by activities that threaten the peace, security, or stability of South Sudan and the surrounding region, including widespread violence and atrocities, human rights abuses, recruitment and use of child soldiers, attacks on peacekeepers, and obstruction of humanitarian operations.

The situation in and in relation to South Sudan continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on April 3, 2014, to deal with that threat must continue in effect beyond April 3, 2019. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13664.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,  
*April 1, 2019.*

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Federal Register

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Tuesday, April 2, 2019

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