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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–1023; Product Identifier 2018–NE–37–AD; Amendment 39–19520; AD 2018–25–09]

RIN 2120–AA64

Airworthiness Directives; CFM International S.A. Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all CFM International S.A. (CFM) LEAP–1B21, –1B23, –1B25, –1B27, –1B28, –1B28B1, –1B28B2, –1B28B2C, –1B28B3, –1B28BBJ1, and –1B28BBJ2 turbofan engines. This AD requires removing certain electronic engine control (EEC) system operation (OPS) and engine health monitoring (EHM) software and installing versions eligible for installation. This AD was prompted by six aborted takeoffs on the similarly designed CFM LEAP–1A model turbofan engine after those engines did not advance to the desired takeoff fan speed due to icing in the pressure sensor line. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 26, 2018.

We must receive comments on this AD by January 25, 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 final rule, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1023.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1023; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Discussion

We received reports of six aborted takeoffs on the similarly designed CFM LEAP–1A model turbofan engine that occurred after those engines did not advance to the desired takeoff fan speed. While we have not received any reports of aborted takeoffs with the CFM LEAP–1B model turbofan engine, the unsafe condition is likely to exist because of similarities in design and instances of ice and moisture found in the pressure sense subsystem lines. The aborted takeoffs happened on the first takeoff of the day after the airplane was exposed to sub-freezing temperatures for more than six hours. After further investigation, the operator found water and ice in the pressure sensor lines, which prevented the pressure sensor from accurately measuring the pressure. As a result, CFM improved the EEC OPS and EHM software to detect and accommodate pressure sensor line freezing. This condition, if not addressed, could result in icing in the pressure sensor lines, inaccurate pressure sensor readings, failure of one or more engines, loss of thrust control, and loss of the airplane. We are issuing this AD to address the unsafe condition on these products.

Related Service Information

We reviewed CFM Service Bulletin (SB) LEAP–1B–73–00–0016–01A–930A–D, Issue 002, dated October 30, 2018. The SB introduces new EEC OPS and EHM software and describes procedures for replacing the software.

FAA's Determination

We are issuing 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.

AD Requirements

This AD requires removing certain EEC OPS and EHM software and installing software that is eligible for installation.

Differences Between the AD and the Service Information

CFM SB LEAP–1B–73–00–0016–01A–930A–D, Issue 002, dated October 30, 2018, recommends that you install the new EEC OPS and EHM software. This AD requires that you install the new EEC OPS and EHM software, and prohibits the use of earlier EEC OPS and EHM software versions.

Interim Action

We consider this AD interim action. CFM is developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved,

and available, we might consider additional rulemaking.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the compliance time for the required action is shorter than the time necessary for the public to comment and for us to publish the final rule. The software must be removed and replaced within 60 days to ensure that icing does not develop in the pressure sensor lines on the affected engines. Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2018–1023 and Product Identifier 2018–NE–37–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the closing date and may amend this final rule 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 final rule.

Costs of Compliance

We estimate that this AD affects 100 engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Software removal and software installation	1 work-hour × $85 per hour = $85	$0	$85	$8,500

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 engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

■ 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):

2018–25–09 CFM International S.A.: Amendment 39–19520; Docket No. FAA–2018–1023; Product Identifier 2018–NE–37–AD.

(a) Effective Date

This AD is effective December 26, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all CFM International S.A. (CFM) LEAP–1B21, –1B23, –1B25, –1B27, –1B28, –1B28B1, –1B28B2, –1B28B2C, –1B28B3, –1B28BBJ1, and –1B28BBJ2 turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7600, Engine Controls.

(e) Unsafe Condition

This AD was prompted by aborted takeoffs on the similarly designed CFM LEAP–1A model turbofan engine after those engines did not advance to the desired takeoff fan speed due to icing in the pressure sensor line. While we have not received any reports of aborted takeoffs with the CFM LEAP–1B model engine, the unsafe condition is likely to exist because of similarities in design and instances of ice and moisture found in the pressure sense subsystem lines. We are issuing this AD to prevent icing in the pressure sensor lines and inaccurate pressure sensor readings. The unsafe condition, if not addressed, could result in failure of one or

more engines, loss of thrust control, and loss of the airplane.

(f) Compliance

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

(g) Required Actions

(1) Within 60 days after the effective date of this AD, remove electronic engine control (EEC) system operation (OPS) software, P/N 2628M86P10 or earlier; and engine health monitoring (EHM) software, P/N 2628M87P10 or earlier, from the engine and from service.

(2) Before further flight after the removal of the EEC OPS and EHM software required by paragraph (g)(1) of this AD, install EEC OPS and EHM software that is eligible for installation.

(h) Installation Prohibition

After 60 days from the effective date of this AD, do not operate any engine identified in paragraph (c) of this AD with EEC OPS software, P/N 2628M86P10 or earlier, installed; or EHM software, P/N 2628M87P10 or earlier, installed.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(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

For more information about this AD, contact Christopher McGuire, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: *chris.mcguire@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on December 3, 2018.

Robert J. Ganley,

Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–26611 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0960; Product Identifier 2018–NM–151–AD; Amendment 39–19512; AD 2018–23–51]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

Editorial Note: Rule document 2018–26365 was originally published on pages 62697 through 62700 in the issue of Thursday, December 6, 2018. In that publication, on page 62700, in Figure 2 to paragraph (h), the last sentence in the table was inadvertently truncated. The corrected document is published here in its entirety.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all The Boeing Company Model 737–8 and –9 airplanes. This emergency AD was sent previously to all known U.S. owners and operators of these airplanes. This AD requires revising certificate limitations and operating procedures of the airplane flight manual (AFM) to provide the flight crew with runaway horizontal stabilizer trim procedures to follow under certain conditions. This AD was prompted by analysis performed by the manufacturer showing that if an erroneously high single angle of attack (AOA) sensor input is received by the flight control system, there is a potential for repeated nose-down trim commands of the horizontal stabilizer. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 21, 2018 to all persons except those persons to whom it was made immediately effective by Emergency AD 2018–23–51, issued on November 7, 2018, which contained the requirements of this amendment.

We must receive comments on this AD by January 22, 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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0960; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Douglas Tsuji, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3548; email: *Douglas.Tsuji@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On November 7, 2018, we issued Emergency AD 2018–23–51, which requires revising certificate limitations and operating procedures of the AFM to provide the flight crew with runaway horizontal stabilizer trim procedures to follow under certain conditions. This emergency AD was sent previously to all known U.S. owners and operators of these airplanes. This action was prompted by analysis performed by the manufacturer showing that if an erroneously high single AOA sensor input is received by the flight control system, there is a potential for repeated nose-down trim commands of the horizontal stabilizer. This condition, if not addressed, could cause the flight crew to have difficulty controlling the airplane, and lead to excessive nose-down attitude, significant altitude loss, and possible impact with terrain.

FAA's Determination

We are issuing 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.

AD Requirements

This AD requires revising certificate limitations and operating procedures of the AFM to provide the flight crew with runaway horizontal stabilizer trim procedures to follow under certain conditions.

Interim Action

We consider this AD interim action. If final action is later identified, we might consider further rulemaking then.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of Emergency AD 2018–23–51, issued on November 7, 2018, to all known U.S. owners and operators of these airplanes. The FAA found that the risk to the flying public justified waiving notice and comment prior to adoption of this rule because an erroneously high single AOA sensor input received by the flight control system can result in a potential for repeated nose-down trim commands of the horizontal stabilizer, which could cause the flight crew to have difficulty controlling the airplane, and lead to excessive nose-down attitude, significant altitude loss, and possible impact with terrain. These conditions still exist and the AD is hereby published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reason(s) stated above, we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2018–0960 and Product Identifier 2018–NM–151–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the closing date and may amend this final rule 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 final rule.

Costs of Compliance

We estimate that this AD affects 45 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revising the AFM	1 work-hour × $85 per hour = $85	$0	$85	$3,825

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

■ 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):

2018–23–51 The Boeing Company: Amendment 39–19512; Docket No. FAA–2018–0960; Product Identifier 2018–NM–151–AD.

(a) Effective Date

This AD is effective December 21, 2018 to all persons except those persons to whom it was made immediately effective by Emergency AD 2018–23–51, issued on November 7, 2018, which contained the requirements of this amendment.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–8 and –9 airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by analysis performed by the manufacturer showing that if an erroneously high single angle of attack (AOA) sensor input is received by the flight control system, there is a potential for repeated nose-down trim commands of the horizontal stabilizer. We are issuing this AD to address this potential resulting nose-down trim, which could cause the flight crew to have difficulty controlling the airplane, and lead to excessive nose-down attitude, significant altitude loss, and possible impact with terrain.

(f) Compliance

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

(g) Revision of Airplane Flight Manual (AFM): Certificate Limitations

Within 3 days after the effective date of this AD, revise the Certificate Limitations chapter of the applicable AFM to include the information in figure 1 to paragraph (g) of this AD.

BILLING CODE 1301–00–D

Figure 1 to paragraph (g) of this AD – *Certificate Limitations*

Required by AD 2018-23-51

Runaway Stabilizer

In the event of an uncommanded horizontal stabilizer trim movement, combined with any of the following potential effects or indications resulting from an erroneous Angle of Attack (AOA) input, the flight crew must comply with the Runaway Stabilizer procedure in the Operating Procedures chapter of this manual:

- Continuous or intermittent stick shaker on the affected side only.
- Minimum speed bar (red and black) on the affected side only.
- Increasing nose down control forces.
- IAS DISAGREE alert.
- ALT DISAGREE alert.
- AOA DISAGREE alert (if the option is installed).
- FEEL DIFF PRESS light.
- Autopilot may disengage.
- Inability to engage autopilot.

(h) AFM Revision: Operating Procedures

Within 3 days after the effective date of this AD, revise the Operating Procedures chapter of the applicable AFM to include the information in figure 2 to paragraph (h) of this AD.

Figure 2 to paragraph (h) of this AD – *Operating Procedures*

Required by AD 2018-23-51

Runaway Stabilizer

Disengage autopilot and control airplane pitch attitude with control column and main electric trim as required. If relaxing the column causes the trim to move, set stabilizer trim switches to CUTOUT. If runaway continues, hold the stabilizer trim wheel against rotation and trim the airplane manually.

Note: The 737-8/-9 uses a Flight Control Computer command of pitch trim to improve longitudinal handling characteristics. In the event of erroneous Angle of Attack (AOA) input, the pitch trim system can trim the stabilizer nose down in increments lasting up to 10 seconds.

In the event an uncommanded nose down stabilizer trim is experienced on the 737-8/-9, in conjunction with one or more of the indications or effects listed below, do the existing AFM Runaway Stabilizer procedure above, ensuring that the STAB TRIM CUTOUT switches are set to CUTOUT and stay in the CUTOUT position for the remainder of the flight.

An erroneous AOA input can cause some or all of the following indications and effects:

- Continuous or intermittent stick shaker on the affected side only.
- Minimum speed bar (red and black) on the affected side only.
- Increasing nose down control forces.
- IAS DISAGREE alert.
- ALT DISAGREE alert.
- AOA DISAGREE alert (if the option is installed).
- FEEL DIFF PRESS light.
- Autopilot may disengage.
- Inability to engage autopilot.

Initially, higher control forces may be needed to overcome any stabilizer nose down trim already applied. Electric stabilizer trim can be used to neutralize control column pitch forces before moving the STAB TRIM CUTOUT switches to CUTOUT. Manual stabilizer trim can be used before and after the STAB TRIM CUTOUT switches are moved to CUTOUT.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle 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) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(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

For more information about this AD, contact Douglas Tsuji, Senior Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3548; email: *Douglas.Tsuji@faa.gov*.

(k) Material Incorporated by Reference

None.

Issued in Des Moines, Washington, on November 21, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. R1–2018–26365 Filed 12–7–18; 2:00 pm]

BILLING CODE 1301–00–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0796; Product Identifier 2018–NM–104–AD; Amendment 39–19518; AD 2018–25–07]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This AD was prompted by reports of drainage holes on the belly fairing forward and middle access panels being obstructed with sealant. This AD requires inspecting for and removing all sealant blocking the drainage holes on the belly fairing forward and middle access panels. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 15, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 15, 2019.

ADDRESSES: For service information identified in this final rule, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0796.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0796; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. The NPRM published in the **Federal Register** on September 18, 2018 (83 FR 47113). The NPRM was prompted by reports of drainage holes on the belly fairing forward and middle access panels being obstructed with sealant. The NPRM proposed to require inspecting for and removing all sealant blocking the drainage holes on the belly fairing forward and middle access panels.

We are issuing this AD to address fluid leakage that could lead to the accumulation of flammable fluids/vapors, beyond the design capacity of the belly fairing venting provisions, which could ignite if an ignition source (*i.e.,* spark, static discharge, heat, etc.) is present.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2018–14, dated May 1, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. The MCAI states:

> Bombardier Aerospace (BA) has informed Transport Canada that the drainage holes on the belly fairing forward and middle access panels may be obstructed with sealant. The purpose of the drainage holes is to allow for drainage of a limited quantity of fluids due to any leaks, should they occur. This condition, if not corrected, may prevent the timely detection of fluid leakage that could lead to the accumulation of flammable fluids/vapors, beyond the design capacity of the belly fairing venting provisions [which could ignite if an ignition source (*i.e.,* spark, static discharge, heat, etc.) is present].
>
> This [Canadian] AD is issued to mandate the removal of all sealant blocking the drainage holes on the belly fairing forward and middle access panels.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0796.

Comments

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

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information for Bombardier Model BD–700–1A10 airplanes.

- Service Bulletin 700–53–051, dated May 17, 2017.
- Service Bulletin 700–53–6009, dated May 17, 2017.

Bombardier has issued the following service information for Bombardier Model BD–700–1A11 airplanes.

- Service Bulletin 700–1A11–53–026, dated May 17, 2017.
- Service Bulletin 700–53–5010, dated May 17, 2017.

This service information describes procedures for inspecting for and removing sealant blocking the drainage holes on the belly fairing forward and middle access panels. These documents are distinct since they apply to different airplane models and configurations. 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 376 airplanes of U.S. registry. We estimate

the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
6 work-hours × $85 per hour = $510	$0	$510	$191,760

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

■ 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):

2018–25–07 Bombardier, Inc.: Amendment 39–19518; Docket No. FAA–2018–0796; Product Identifier 2018–NM–104–AD.

(a) Effective Date

This AD is effective January 15, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers 9001 through 9707 inclusive, 9709 through 9717 inclusive, 9719 through 9726 inclusive, 9728, 9730, 9732 through 9734 inclusive, 9736 through 9740 inclusive, 9742 through 9745 inclusive, 9749, 9751, 9757, and 9998.

(d) Subject

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

(e) Reason

This AD was prompted by reports of drainage holes on the belly fairing forward and middle access panels being obstructed with sealant. We are issuing this AD to address fluid leakage that could lead to the accumulation of flammable fluids/vapors, beyond the design capacity of the belly fairing venting provisions, which could ignite if an ignition source (*i.e.,* spark, static discharge, heat, etc.) is present.

(f) Compliance

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

(g) Sealant Removal

Within 375 flight hours or 12 months, whichever occurs first, after the effective date of this AD, do a general visual inspection for and remove all sealant blocking the drainage holes on the belly fairing forward and middle access panels, in accordance with the Accomplishment Instructions of the applicable service information listed in figure 1 to paragraph (g) of this AD.

Figure 1 to paragraph (g) of this AD – *Service bulletins*

Airplane Model	Bombardier Service Bulletin	Issue Date
BD-700-1A10	700-53-051	May 17, 2017
BD-700-1A10	700-53-6009	May 17, 2017
BD-700-1A11	700-1A11-53-026	May 17, 2017
BD-700-1A11	700-53-5010	May 17, 2017

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2018–14, dated May 1, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0796.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7323; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov*.

(j) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 700–1A11–53–026, dated May 17, 2017.

(ii) Bombardier Service Bulletin 700–53–051, dated May 17, 2017.

(iii) Bombardier Service Bulletin 700–53–5010, dated May 17, 2017.

(iv) Bombardier Service Bulletin 700–53–6009, dated May 17, 2017.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* internet *http://www.bombardier.com*.

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

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Des Moines, Washington, on November 23, 2018.

John P. Piccola,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–26534 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–1013; Airspace Docket No. 18–ANE–7]

RIN 2120–AA66

Amendment of VOR Federal Airways V–318 and V–352; Northeastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the descriptions of VHF Omnidirectional Range (VOR) Federal airways V–318 and V–352 to reflect the removal of certain route segments within Canadian airspace that were deleted by NAV CANADA. This rule modifies the above airway descriptions to match the current configuration of the routes.

DATES: Effective date 0901 UTC, February 28, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the descriptions of VOR Federal airways V–318 and V–352 to maintain the accuracy of navigation publications.

Background

NAV CANADA is the company that operates Canada's civil air navigation service. As part of Canada's efforts to expand the availability of area navigation (RNAV) routing, NAV CANADA has amended certain routes that traverse both Canadian and United States airspace. In this case, the descriptions of VOR Federal airways V–318 and V–352, as published in FAA Order 7400.11C, originate in Canadian airspace, then traverse through United States airspace (in the State of Maine) then reenter Canadian airspace.

The current route description of V–318 extends between the Quebec, PQ, Canada, VORTAC and the St John, NB, Canada, VOR/DME. NAV CANADA has deleted that segment at the western end of V–318 that runs between the Quebec VORTAC and the United States/Canadian border, at the PINTE, Canada, navigation fix. Therefore, the FAA is removing that segment from the V–318 description. The remainder of the route from the PINTE fix to the Houlton, ME, VOR/DME, and on to the St John, Canada VOR/DME remains in effect as currently charted.

The current route description of V–352 extends between the Beauce, PQ, Canada VORTAC and the Fredericton, NB, Canada, VOR/DME. NAV CANADA has deleted the segment on the western end of the route between the Beauce VORTAC and the DEPRI, ME, waypoint (WP) at the United States/Canadian border. Additionally, NAV CANADA has deleted the route segment on the eastern end of the route between the Houlton, ME, VOR/DME and the Fredericton, NB, VOR/DME. FAA is amending the description of V–352 to remove the segments deleted by NAV CANADA. The amended V–352 lies totally within United States airspace and extends between PATTA, ME, navigation fix (defined by the intersection of the Beauce, PQ, Canada VOR/DME 085°(T)/100°(M) and the Bangor, ME, VORTAC 336°(T)/355°(M) radials) and the Houlton, ME, VOR/DME.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document will be subsequently amended in the Order.

Availability and Summary of Documents for Incorporation by Reference

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

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying the descriptions of VOR Federal airways V–318 and V–352 to remove certain route segments in Canadian airspace.

V–318: NAV CANADA has deleted the route segment that extends between the Quebec VORTAC and the PINTE navigation fix (located on the United States/Canadian border). The FAA is amending the description of V–318 by removing the words ''From Quebec, Province of Quebec, Canada, 81 miles 65 MSL, 26 miles 85 MSL,'' and replacing them with the words ''From INT Beauce, PQ, Canada 103°(T)/119°(M) and Quebec, PQ, Canada 047°(T)/062°(M) radials.'' The new wording defines the PINTE fix. The remainder the route description to St John, NB, Canada, is unchanged.

The amended V–318 description reads:

''From INT Beauce, PQ, Canada 103° and Quebec, PQ, Canada 047° radials; Houlton, ME; INT Houlton 128° and St John, NB, Canada 267° radials; to St John. The airspace in Canada is excluded.''

V–352: NAV CANADA has deleted the route segments between the Beauce, PQ, Canada, VOR/DME and the United States/Canadian border; and the segments between the Houlton, ME, VOR/DME and the Fredericton, NB, Canada, VOR/DME.

The FAA is amending the description of V–352 by removing the words ''From Beauce, Quebec, Canada, via'' and replacing them with the words ''From INT Beauce, PQ, Canada 085°(T)/100°(M) and Bangor, ME 336°(T)/355°(M) radials; to'' and removing the words ''to Fredericton, NB, Canada, excluding the airspace in Canada.'' The amended route is entirely within United States airspace.

The amended V–352 description reads:

''From INT Beauce, PQ, Canada 085° and Bangor, ME, 336° radials; to Houlton, ME.''

Note: For reference, both True and Magnetic degrees are shown where new navigation aid radials are added in the above descriptions. Per standard practice, only True degrees are stated in the amended route descriptions as listed in ''The Amendment'' section, below.

Because this amendment is necessary to update the descriptions of V–318 and V–352 by removing airway segments in Canadian airspace that have been deleted by NAV CANADA, I find that notice and public procedure under 5 U.S.C. 553(b) are impractical and contrary to the public interest. This action is necessary to ensure agreement between navigation databases and accurate depiction of the routes on aeronautical charts.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is

certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action, of modifying the descriptions of VOR Federal airways V–318 and V–352 to reflect the removal of certain route segments within Canadian airspace deleted by NAV CANADA, qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F—Environmental Impacts: Policies and Procedures, Paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). This action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–318 [Amended]

From INT Beauce, PQ, Canada 103° and Quebec, PQ, Canada, 047° radials; Houlton, ME; INT Houlton 128° and St John, NB, Canada, 267° radials; to St John. The airspace within Canada is excluded.

V–352 [Amended]

From INT Beauce, PQ, Canada 085° and Bangor, ME 336° radials; to Houlton, ME.

* * * * *

Issued in Washington, DC, on December 3, 2018.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–26678 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2016–N–2462]

RIN 0910–AH35

List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations to revise the list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. Drug products appearing on this list may not be compounded under the exemptions provided by sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, the final rule adds two entries to this list of drug products.

DATES: This rule is effective January 10, 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: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Regulatory Action

FDA is amending its regulations to revise the list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (referred to as ''the withdrawn or removed list'' or ''the list'') (§ 216.24 (21 CFR 216.24)). Drug products appearing on the withdrawn or removed list may not be compounded under the exemptions provided by sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b). In this final rule, the Agency is finalizing in part the proposed amendments to § 216.24 set forth in the proposed rule published in the **Federal Register** of October 18, 2016 (81 FR 71648).

B. Summary of the Major Provisions of the Regulatory Action

After soliciting public comments and consulting with the FDA Pharmacy Compounding Advisory Committee (the Committee), we are adding the following entries to the list in § 216.24 of drug products that have been withdrawn or removed from the market because such drug products or

components of such drug products have been found to be unsafe or not effective:

Bromocriptine mesylate: All drug products containing bromocriptine mesylate for prevention of physiological lactation.

Ondansetron hydrochloride: All intravenous drug products containing greater than a 16 milligram (mg) single dose of ondansetron hydrochloride.

C. Legal Authority

Sections 503A, 503B, and 701(a) of the FD&C Act (21 U.S.C. 353a, 353b, and 371(a)) provide the principal legal authority for this final rule.

D. Costs and Benefits

The Agency is not aware of routine compounding of the drug products that are the subject of this final rule. Therefore, we do not estimate any compliance costs or loss of sales as a result of the prohibition against compounding these drug products for human use. The Agency has determined that this rulemaking is not a significant regulatory action as defined by Executive Order 12866.

II. Background

A. Relevant Provisions of the Statute

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of new drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

In addition, section 503B of the FD&C Act describes the conditions that must be satisfied for a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility to be exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security).

One of the conditions that must be satisfied for a drug product to qualify for the exemptions under sections 503A or 503B of the FD&C Act is that the compounder does not compound a drug product that appears on a list published by the Secretary of Health and Human Services (the Secretary) (delegated to FDA) of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (the withdrawn or removed list) (see sections 503A(b)(1)(C), 503B(a)(4), and 503B(a)(11) of the FD&C Act).

B. The List of Drug Products in § 216.24

The drug products listed in the withdrawn or removed list codified at § 216.24 have been withdrawn or removed from the market because they have been found to be unsafe or not effective. A drug product that is included in the withdrawn or removed list is not eligible for the exemptions provided in section 503A(a) from sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act. In addition, a drug that is included in the withdrawn or removed list is not eligible for the exemptions provided in section 503B(a) from sections 502(f)(1), 505, and 582 of the FD&C Act.

C. Regulatory History of the List

The Food and Drug Modernization Act of 1997 (Pub. L. 105–115) added section 503A to the FD&C Act. On October 8, 1998, FDA proposed a rule in the **Federal Register** (63 FR 54082) to establish the original withdrawn or removed list. On March 8, 1999, FDA finalized this rule (64 FR 10944), prohibiting the products described on the original list from being compounded under the exemptions provided by section 503A(a) of the FD&C Act.

Following the addition of section 503B to the FD&C Act on November 27, 2013, through the enactment of the Drug Quality and Security Act (Pub. L. 113–54), FDA published a proposed rule to revise and update the list in § 216.24 on July 2, 2014 (79 FR 37687); FDA published the final rule to amend § 216.24 in the **Federal Register** of October 7, 2016 (81 FR 69668) (2016 final rule). Given that nearly identical criteria apply for a drug to be included on the list referred to in section 503A(b)(1)(C) and the list referred to in section 503B(a)(4) of the FD&C Act, the 2016 final rule added language to § 216.24 clarifying that it applies for purposes of both sections 503A and 503B.

III. Proposed Rule and Final Rule

A. Presentation to the Advisory Committee

At a meeting held on June 17 and 18, 2015 (see the **Federal Register** of May 22, 2015 (80 FR 29717)), FDA presented to the Committee FDA's proposal to add to the withdrawn or removed list all drug products containing more than 325 mg of acetaminophen per dosage unit, all drug products containing aprotinin, all drug products containing bromocriptine mesylate for the prevention of physiological lactation, and all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride. The Committee voted in favor of including each drug product entry on the list as proposed by FDA.[1]

B. The Proposed Rule

In the **Federal Register** of October 18, 2016, FDA proposed to revise the withdrawn or removed list to add all drug products containing aprotinin, all drug products containing bromocriptine mesylate for the prevention of physiological lactation, and all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride (October 2016 proposed rule). The addition of all drug products containing more than 325 mg of acetaminophen per dosage unit to the list was not included in the October 2016 proposed rule and remains under consideration by the Agency.

C. The Final Rule

The Agency has considered the public discussion and the advice provided by the Committee regarding these matters at the June 2015 meeting, as well as the October 2016 proposed rule, including the comments submitted on the proposed rule (see section IV). Based on the information before FDA and its own knowledge and expertise, FDA is adding two entries from the proposed rule to the withdrawn or removed list in § 216.24.

The two entries FDA is adding to § 216.24 are as follows:

Bromocriptine mesylate: All drug products containing bromocriptine mesylate for prevention of physiological lactation.

Ondansetron hydrochloride: All intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride.

At this time, FDA is not finalizing the entry in the proposed rule for all drug products containing aprotinin. The addition of an entry to the withdrawn or removed list for drug products containing aprotinin remains under consideration by FDA.

[1] A transcript of the June 2015 Committee meeting (Ref. 1) and briefing information that includes reviews and background on the proposed entries (Ref. 2) may be found at the Dockets Management Staff (see **ADDRESSES**) and at *https://wayback.archive-it.org/7993/20170111202622/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm431285.htm.*

IV. Comments on the Proposed Rule and FDA's Responses

Four comments, all from individuals, were submitted on the October 2016 proposed rule. FDA has summarized and responded to the relevant comments in the following paragraphs. A comment about ''hernia repair with mesh and plug'' has not been answered because it was not relevant to this rulemaking. Comments regarding the proposed addition of an entry to the withdrawn or removed list for aprotinin will not be answered at this time because the entry remains under consideration by FDA.

To make it easier to identify the comments and FDA's responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before the Agency's response. We have numbered each comment to help distinguish between different comments. Similar comments are grouped together under the same number, and, in some cases, different subjects discussed in the same comment are separated and designated as distinct comments for purposes of FDA's response. 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 the comments were received.

A. Comments on Proposed Entries for Inclusion on the List

1. Bromocriptine Mesylate

(Comment 1) One comment supported the proposal to include all drug products containing bromocriptine mesylate for prevention of physiological lactation on the withdrawn or removed list.

(Response 1) FDA agrees with the comment.

(Comment 2) FDA received one comment opposing the proposal to include all drug products containing bromocriptine mesylate for prevention of physiological lactation on the withdrawn or removed list. The comment asserts that bromocriptine mesylate offers ''significant improvements in the quantity and quality of life,'' and, although it has ''serious adverse effects,'' the benefits of bromocriptine mesylate compared to its risks ''should warrant continuous approvability.''

(Response 2) FDA disagrees with the comment. For the reasons that follow, FDA will add all drug products containing bromocriptine mesylate for prevention of physiological lactation to the list in § 216.24.

As a preliminary matter, the issue in this rulemaking is whether all drug products containing bromocriptine mesylate for the indication of prevention of physiological lactation were withdrawn or removed from the market because they were found to be unsafe or not effective for this indication. The criteria that must be met to place a drug product on the withdrawn or removed list are laid out in the FD&C Act. Under sections 503A and 503B of the FD&C Act, to be placed on the withdrawn or removed list, drug products must have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.

As FDA previously explained in the October 2016 proposed rule, FDA withdrew approval of PARLODEL (bromocriptine mesylate, NDA 17962) for the indication of prevention of physiological lactation in a document published in the **Federal Register** of January 17, 1995 (60 FR 3404). At the time, PARLODEL was the only marketed drug product containing bromocriptine mesylate labeled with this indication. FDA's 2015 ''Review of Bromocriptine Mesylate for the Withdrawn or Removed List'' indicates that the 1995 withdrawal of PARLODEL for prevention of physiological lactation was based on the unfavorable benefit-risk balance of this product for this indication. See ''Review of Bromocriptine Mesylate for the Withdrawn or Removed List'' in the FDA Briefing Document for the June 17 and 18, 2015 Pharmacy Compounding Advisory Committee Meeting, available at *https://wayback.archive-it.org/7993/20170113060809/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm449533.htm.* In particular, in a notice published in the **Federal Register** on August 23, 1994 (59 FR 43347), FDA concluded that bromocriptine mesylate's risks of hypertension, seizures, and cardiovascular accidents outweighed the product's marginal benefit in preventing postpartum lactation, which can be suppressed without risk by using more conservative, nonpharmacological treatments. Withdrawal of PARLODEL's indication for the prevention of physiological lactation became effective on February 16, 1995 (60 FR 3404). FDA has determined that all drug products containing bromocriptine mesylate for prevention of physiological lactation were withdrawn or removed from the market because such products have been found to be unsafe or not effective. We note that FDA-approved drug products containing bromocriptine mesylate for other indications, such as treatment of Parkinson's disease, acromegaly, and prolactin-secreting adenomas, remain marketed.

FDA's 2015 review, which included a discussion of the withdrawal of PARLODEL's indication for the prevention of physiological lactation, was presented to the Committee at the meeting held on June 17 and 18, 2015, and the Committee voted in favor of the Agency's proposal to include all drug products containing bromocriptine mesylate for the prevention of physiological lactation on the list. For these reasons, FDA proposed in the October 2016 proposed rule to include all drug products containing bromocriptine mesylate for the prevention of physiological lactation on the withdrawn or removed list.

The comment offered no scientific rationale or support for its position that this drug product should not be on the list; therefore, FDA is including bromocriptine mesylate for prevention of physiological lactation on the withdrawn or removed list.

2. Ondansetron Hydrochloride

(Comment 3) One comment supported the proposal to include all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride on the withdrawn or removed list.

(Response 3) FDA agrees with the comment.

(Comment 4) FDA received one comment on the proposal to include all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride suggesting ''perhaps there is more to investigate and stricter regulation of the administration of IV ondansetron hydrochloride is warranted in the future.''

(Response 4) FDA intends to monitor future approvals, withdrawals, or removals of drugs, to consider other relevant information that may suggest the need to revise the withdrawn or removed list, and to propose modifications as appropriate. In addition, members of the public can submit a citizen petition at any time under 21 CFR 10.25 and 10.30 requesting that FDA add, modify, or remove an entry on the list (with data to support their request), and FDA will consider and respond to the petition.

(Comment 5) FDA received one comment opposing the proposal to include all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride on

the withdrawn or removed list. The comment asserts that ondansetron hydrochloride offers ''significant improvements in the quantity and quality of life,'' and, although it has ''serious adverse effects,'' the benefits of ondansetron hydrochloride compared to its risks ''should warrant continuous approvability.''

(Response 5) FDA disagrees with the comment. For the reasons that follow, FDA will add all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride to the list in § 216.24.

As noted earlier, the issue in this rulemaking is whether drug products containing greater than a 16 mg single dose of ondansetron hydrochloride were withdrawn or removed from the market because they were found to be unsafe or not effective.

As FDA previously explained in the October 2016 proposed rule, in the **Federal Register** of June 10, 2015 (80 FR 32962), FDA announced its determination under 21 CFR 314.161 and 314.162(a)(2) that the NDA for Ondansetron (ondansetron hydrochloride) Injection, USP, 32 mg/50 mL, single IV dose was withdrawn from sale for reasons of safety. In particular, this product was associated with a specific type of irregular heart rhythm called QT interval prolongation, and the data suggest that any dose above the maximum recommendation of 16 mg per dose intravenously has the potential for increased risk of QT prolongation. FDA made this determination after holders of one NDA and four ANDAs voluntarily removed such products from the market and requested that FDA withdraw approval of their respective applications under 21 CFR 314.150(d). Thus, all drug products containing greater than a 16 mg single dose of ondansetron hydrochloride have been withdrawn or removed from the market because such drug products have been found to be unsafe or not effective. We note that FDA-approved drug products containing lower single doses of ondansetron hydrochloride remain marketed.

FDA's review of intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride was presented to the Committee at the meeting held on June 17 and 18, 2015, and the Committee voted in favor of the Agency's proposal to include all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride on the list. For these reasons, FDA proposed in the October 2016 proposed rule to include all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride on the withdrawn or removed list.

(Comment 6) FDA received one comment asserting that ondansetron hydrochloride should not be recommended for use by pregnant women because it was not approved by FDA for pregnant women.

(Response 6) This comment is outside the scope of this rulemaking. Compounded drugs are not FDA approved and this rulemaking addresses the placement of certain drug products on the withdrawn or removed list, including all intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride. As previously noted, drugs appearing on this list may not be compounded under the exemptions provided by sections 503A and 503B of the FD&C Act. Therefore, to the extent the commenter believes that intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride should not be compounded for pregnant women under the exemptions provided by sections 503A and 503B of the FD&C Act, we agree. The addition of the entry FDA is finalizing regarding ondansetron hydrochloride through this rulemaking for the list in § 216.24 will prohibit compounding of intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride under the exemptions provided by sections 503A and 503B of the FD&C Act for all patients, including pregnant women.

V. Legal Authority

Sections 503A and 503B of the FD&C Act provide the principal legal authority for this final rule. As described previously in section II, section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act (sections 501(a)(2)(B), 502(f)(1), and 505). One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the licensed pharmacist or licensed physician does not compound a drug product that appears on a list published by FDA in the **Federal Register** of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see section 503A(b)(1)(C) of the FD&C Act). Section 503A(c)(1) of the FD&C Act also states that the Secretary shall issue regulations to implement section 503A, and that before issuing regulations to implement section 503A(b)(1)(C) pertaining to the withdrawn or removed list, among other sections, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health.[2]

Section 503B of the FD&C Act describes the conditions that must be satisfied for a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility to be exempt from three sections of the FD&C Act (sections 502(f)(1), 505, and 582). One of the conditions in section 503B of the FD&C Act that must be satisfied to qualify for the exemptions is that the drug does not appear on a list published by FDA of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective (see section 503B(a)(4)). To be eligible for the exemptions in section 503B, a drug must be compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with section 503B, including as provided in section 503B(a)(4) of the FD&C Act.

Thus, sections 503A and 503B of the FD&C Act, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as our principal legal authority for this final rule revising FDA's regulation on the list of drug products withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective in § 216.24.

VI. Analysis of Environmental Impact

We have 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. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Analysis of Impacts

We have examined the impacts of the final 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

[2] *Note:* The functions of the Secretary described herein have been delegated to FDA.

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.'' This final rule is not a significant regulatory action as defined by Executive Order 12866 and is not subject to Executive Order 13771.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small businesses are not expected to incur any compliance costs or loss of sales due to this regulation, we certify that the 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 is not expected to result in an expenditure in any year that would meet or exceed this amount.

This final rule amends § 216.24 concerning human drug compounding. Specifically, the final rule adds to the list of drug products that may not be compounded under the exemptions provided by sections 503A and 503B of the FD&C Act because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see section II). We are adding two entries to the list: Drug products containing bromocriptine mesylate for prevention of physiological lactation and intravenous drug products containing greater than a 16 mg single dose of ondansetron hydrochloride. The Agency is not aware of routine compounding of these drug products; therefore, we do not estimate any compliance costs or loss of sales as a result of the prohibition against compounding these drugs for human use.

Unless we certify that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options to minimize any significant economic impact of a regulation on small entities. Most pharmacies meet the Small Business Administration definition of a small entity, which is defined as having annual sales less than $27.5 million for this industry. We are not aware of any routine compounding of the drug products that are the subject of this final rule and do not estimate any compliance costs or loss of sales to small businesses as a result of the prohibition against compounding these drug products. Therefore, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

VIII. Paperwork Reduction Act of 1995

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

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 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.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final 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, the Agency concludes 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.

XI. 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. Transcript for the June 17–18, 2015, Meeting of the Pharmacy Compounding Advisory Committee, available at *https://wayback.archive-it.org/7993/20170111202622/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm431285.htm.*

2. Briefing Information for the June 17–18, 2015, Meeting of the Pharmacy Compounding Advisory Committee, available at *https://wayback.archive-it.org/7993/20170111202622/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm431285.htm.*

List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 216 is amended as follows:

PART 216—HUMAN DRUG COMPOUNDING

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

■ 2. Amend § 216.24 by adding, in alphabetical order, to the list of drugs ''Bromocriptine mesylate'' and ''Ondansetron hydrochloride'' to read as follows:

§ 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

* * * * *

Bromocriptine mesylate: All drug products containing bromocriptine mesylate for prevention of physiological lactation.

* * * * *

Ondansetron hydrochloride: All intravenous drug products containing greater than a 16 milligram single dose of ondansetron hydrochloride.

* * * * *

Dated: December 4, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–26712 Filed 12–10–18; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2018–HA–0062]

RIN 0720–AB75

TRICARE Pharmacy Benefits Program Reforms

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: This interim final rule implements Section 702 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18). The law makes significant changes to the TRICARE Pharmacy Benefits Program, specifically it: Updates co-payment requirements; authorizes a new process for encouraging use of pharmaceutical agents that provide the best clinical effectiveness by excluding coverage for particular pharmaceutical agents that provide very little or no clinical effectiveness relative to similar agents and for giving preferential status to agents that provide enhanced clinical effectiveness; and authorizes special reimbursement methods, amounts, and procedures to encourage use or high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers.

DATES: This interim final rule is effective December 11, 2018. Comments must be received by February 11, 2019.

FOR FURTHER INFORMATION CONTACT: David W. Bobb, RPh, JD, Chief, Pharmacy Operations, Defense Health Agency (DHA), telephone (703) 681–2890.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Interim Final Rule

This interim final rule implements Section 702 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18), which does three things: (1) It updates cost-sharing requirements for outpatient pharmaceutical prescriptions filled by retail pharmacies and the TRICARE mail order pharmacy program. (2) It authorizes a new Uniform Formulary process for encouraging use of pharmaceutical agents in the TRICARE Pharmacy Benefits Program that provide the best clinical effectiveness by excluding coverage for particular pharmaceutical agents that provide very little or no clinical effectiveness relative to similar agents and giving preferential status to agents that provide enhanced clinical effectiveness. (3) It authorizes special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. This interim final rule implements each of these three statutory changes. This is being issued as an interim final rule in order to implement expeditiously the reforms authorized by Section 702, as specifically authorized by subsection (b)(3) of that section. Based on that clear Congressional authority and intent, the Department finds that obtaining public comment in advance of issuing this rule is impracticable, unnecessary, and contrary to the public interest. Delaying expeditious implementation by waiting for public comments to this interim rule not only delays the significant cost savings to the government that will be realized through implementation but also continues to allow coverage of pharmaceutical agents that do not provide the best clinical effectiveness for beneficiaries. In addition, subsection (b)(3) of Section 702 states that ''in order to implement expeditiously the reforms authorized . . . (A) the Secretary of Defense may prescribe an interim final rule, (B) not later than one year after prescribing the interim final rule and considering public comments with respect to such interim final rule, by prescribing a final rule.'' Clearly Congressional intent is to implement the authorized reforms quickly. Nonetheless, DoD invites public comments on this rule and is committed to considering all comments and issuing a final rule as soon as practicable (but not later than one year after issuance of this interim final rule).

B. Legal Authority for the Regulatory Action

This interim final rule is under the primary authority of 10 U.S.C. 1074g, 1079 and 1086, and Section 702 of NDAA–18. Specifically, section 702(b)(3) of NDAA–18 authorizes DoD to ''prescribe such changes to the regulations implementing the TRICARE program . . . by prescribing an interim final rule.'' TRICARE program regulations (32 CFR part 199) are issued under statutory authorities including 10 U.S.C. 1074g (the Pharmacy Benefits Program) and 10 U.S.C. 1079 and 1086 (TRICARE medical benefits). Section 702 of NDAA–18 amends both section 1074g and section 1079 (the section 1079 amendment being automatically applicable to section 1086).

C. Summary of Major Provisions of the Interim Final Rule

The major provisions of the interim final rule are the following.

1. *Updating Cost-Sharing.* Under the authority of section 1074g(a)(6), as amended by Section 702(a) of NDAA FY18, we are amending 32 CFR 199.21(i) to cross reference the statutory changes.

2. *Uniform Formulary Changes.* Based on section 1074g(a)(10), as added by Section 702(b)(1) of NDAA FY 18, we are changing the Uniform Formulary process under 32 CFR 199.21(e) by authorizing the exclusion of any pharmaceutical agent that provides very little or no clinical effectiveness relative to similar agents, and preferential status for pharmaceutical agents that have enhanced clinical effectiveness relative to similar agents.

3. *Pharmaceutical Agents as Part of Medical Services.* Based on 10 U.S.C. 1079(q), as added by Section 702(b)(2) of NDAA FY18, we are changing provisions of 32 CFR 199.14 to authorize the adoption of special reimbursement methods, amounts and procedures to encourage the use of high value products and discourage the use of low value products—both relative to similar agents—in connection with pharmaceutical agents provided as part of outpatient medical services covered by TRICARE.

II. Provisions of Interim Final Rule

A. Updating Co-Payments

The interim final rule amends 32 CFR 199.21(i)(2), which is the paragraph of the TRICARE regulation that governs cost-sharing amounts under the Pharmacy Benefits Program. The amended language simply cross references the statutory specifications on cost-sharing, including the table set forth in 10 U.S.C. 1074g(a)(6)(A). This table lists cost sharing amounts for the years 2018 through 2027 for generic, formulary, and non-formulary pharmaceutical agents dispensed by retail network pharmacies and the mail order pharmacy program. Two exceptions are that there is a $0 cost-share for vaccines/immunizations authorized as preventive care for eligible beneficiaries and provided by

retail network pharmacies and a $0 cost-share for smoking cessation pharmaceutical agents covered under the smoking cessation program. Another special rule under the statute is that for survivors of members who die on active duty and for disability retirees and their families, cost-sharing increases will not apply, and the 2017 amounts will remain in effect. The interim final rule also provides that for any year after 2027, the cost-sharing amounts will reflect changes in the costs of pharmaceutical agents and prescription dispensing, calculated separately for generic, formulary, and non-formulary drugs in each applicable point of service.

B. Uniform Formulary Changes

The interim final rule amends 32 CFR 199.21(e)(3) to provide that the Pharmacy and Therapeutics Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Such special actions may operate as exceptions to the normal rules and procedures. Specifically, the Pharmacy and Therapeutics Committee may recommend complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents—*i.e.,* other pharmaceutical agents in the same drug class—to covered beneficiaries and DoD. A partial exclusion under this paragraph may take the form (as one example) of a limitation on the clinical conditions, diagnoses, or indications for which the pharmaceutical agent may be prescribed. (As an example of this, off-label uses of a pharmaceutical agent may be disallowed.) A partial exclusion may be implemented through preauthorization or other means recommended by the Pharmacy and Therapeutics Committee. In the case of a partial exclusion, a pharmaceutical agent may be available on the non-formulary tier of the uniform formulary for limited purposes and for other purposes be excluded. In addition, the Pharmacy and Therapeutics Committee may recommend to the Director giving preferential status—based on a determination of enhanced clinical effectiveness relative to other agents in the same drug class—to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of cost-sharing as a generic product.

C. Pharmaceutical Agents as Part of Medical Services

The interim final rule amends 32 CFR 199.14(a)(6) and (j)(1) to provide that TRICARE may adopt special reimbursement methods, amounts, and procedures to encourage the use of high-value pharmaceutical agents as part of medical services furnished in a hospital outpatient setting or as part of any other medical services provided to TRICARE beneficiaries. Although TRICARE generally follows Medicare's reimbursement methodology when practicable for such medical services which include medically necessary administration of drugs, Section 702(b)(2) of NDAA FY18 authorizes the adoption of special reimbursement methods when determined appropriate to encourage the use of high-value pharmaceutical agents and discourage the use of low-value agents. For example, Medicare's reimbursement formula for physician-administered drugs paid under Part B is Average Sales Price (ASP) + 6%. Medicare and TRICARE reimburse providers ASP + 6 percent for the drug regardless of the price a provider pays for the drug.

Both Medicare and TRICARE acknowledge that such payment for physician-administered drugs does not incentivize high-value clinically driven, low cost drugs. To the contrary, the payment methods for physician-administered drugs using the ASP plus 6 percent raises many concerns including that it may encourage the use of more expensive drugs because the 6% add-on generates more revenue for more expensive drugs without regard to the relative clinical value of the product compared to other products in the same drug class. In order to remove the incentive for using higher priced products that have no higher clinical value, TRICARE may utilize the authority provided by the NDAA–18 to restructure—at least for certain selected drug classes, or categories of pharmaceuticals (identified in coordination with the Pharmacy and Therapeutics Committee, or other entities as described in the implementing instructions)—the reimbursement amount. For example, TRICARE is evaluating established the ASP add-on as a percentage (likely 6 percent) of the median value of all drugs in a particular class, rather than attaching the 6% add-on to the ASP of a particular drug. The specific modifications to drug pricing for physician-administered drugs authorized by this IFR and NDAA FY18 shall be published in TRICARE's implementing instructions (manuals) as approved by the Director, DHA, and shall be published on the health.mil website. The amendment to § 199.14(j)(1) will authorize this.

III. Regulatory Procedures

Interim Final Rule Justification

This is being issued as an interim final rule in order to implement expeditiously the reforms authorized by Section 702, as specifically authorized by subsection (b)(3) of that section. Based on that clear Congressional authority and intent, the Department finds that obtaining public comment in advance of issuing this rule is impracticable, unnecessary, and contrary to the public interest.

Executive Order (E.O.) 13771, ''Reducing Regulation and Controlling Regulatory Costs''

E.O. 13771 seeks to control costs associated with the government imposition of private expenditures required to comply with Federal regulations and to reduce regulations that impose such costs. Consistent with the analysis of transfer payments under OMB Circular A–4, this interim final rule does not involve regulatory costs subject to E.O. 13771. Rather, this interim final rule affects only health care reimbursement payments under the TRICARE program. Aside from the ''housekeeping'' change to the regulation to incorporate the updated copayment amounts enacted by Congress, the interim final rule makes two changes to the program: a new authority under the Uniform Formulary process and revised payment authority for pharmaceutical agents as part of medical services.

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This interim final rule has been designated a ''significant regulatory action,'' although not economically significant, under section

3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget (OMB).

The economic effect of these changes is limited to government reimbursements to health care providers/suppliers that under Circular A–4 are not considered as costs imposed on the economy. The expected reduction in government payments to pharmaceutical companies is based on some predicted increase in use of higher value medications and a corresponding decrease in the use of lower value medications in drug classes where different drugs have comparable clinical effect. The expected value of this shift in use of some medications—*i.e.,* the quantity of the transfer payments—is $30 million per year.

An initial analysis identified a sample group of candidate drugs that do not offer additional therapeutic benefit over other formulary items. By comparing the current costs to those of a lower-priced comparator and assuming similar utilization rates, the average cost avoidance was $1.5M/drug/year, with a more conservative cost avoidance of $1M/drug/year. When fully implemented, this new process could average 30 drugs per year at a conservative cost avoidance of $1M/drug/year.

Congressional Review Act, 5 U.S.C. 804(2)

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100M or more or have certain other impacts. This final rule is not a major rule under the Congressional Review Act.

Public Law 96–354, ''Regulatory Flexibility Act'' (RFA), (5 U.S.C. 601)

The Regulatory Flexibility Act requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This interim final rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this rule is not subject to the requirements of the RFA.

Public Law 104–4, Sec. 202, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100M in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $140M. This interim final rule will not mandate any requirements for state, local, or tribal governments or the private sector.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This rulemaking does not contain a ''collection of information'' requirement, and will not impose additional information collection requirements on the public under Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. chapter 35).

Executive Order 13132, ''Federalism''

This interim final rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the national Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel.

For the reasons stated in the preamble, the DoD amends 32 CFR part 199 as set forth below:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Section 199.14 is amended by revising paragraphs (a)(6)(i)(I) and (a)(6)(ii), and by adding paragraph (j)(1)(xi), to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

(a) * * *

(6) * * *

(i) * * *

(I) *Drugs administered other than by oral method.* Drugs administered other than by oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than by oral method covered by the allowable charge method under paragraph (j)(1) of this section.

* * * * *

(ii) *Outpatient services subject to OPPS*—(A) *General.* Outpatient services provided in hospitals subject to Medicare OPPS as specified in 42 CFR 413.65 and 42 CFR 419.20 will be paid in accordance with the provisions outlined in sections 1833t of the Social Security Act and its implementing Medicare regulation (42 CFR part 419) subject to exceptions as authorized by this paragraph (a)(6)(ii).

(B) Under the above governing provisions, TRICARE will recognize to the extent practicable, in accordance with 10 U.S.C. 1089(j)(2), Medicare's OPPS reimbursement methodology to include specific coding requirements, ambulatory payment classifications (APCs), nationally established APC amounts and associated adjustments (*e.g.,* discounting across geographical regions and outlier calculations).

(C) While TRICARE intends to remain as true as possible to Medicare's basic OPPS methodology, there will be some deviations required to accommodate TRICARE's unique benefit structure and beneficiary population as authorized under the provisions of 10 U.S.C. 1079(j)(2).

(D) TRICARE is also authorized to deviate from Medicare's basic OPPS methodology to establish special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. Therefore, drugs administered other than oral method provided on an outpatient basis by hospitals are paid on the same basis as drugs administered other than oral method covered by the allowable charge method under paragraph (j)(1) of this section.

(E) *Temporary transitional payment adjustments (TTPAs).* Temporary transitional payment adjustments will be in place for all hospitals, both network and non-network, in order to buffer the initial decline in payments upon implementation of TRICARE's OPPS.

(*1*) *For network hospitals.* The temporary transitional payment adjustments will cover a four-year period. The four-year transition will set higher payment percentages for the ten Ambulatory Payment Classification

(APC) codes 604–609 and 613–616, with reductions in each of the transition years. For non-network hospitals, the adjustments will cover a three year period, with reductions in each of the transition years. For network hospitals, under the TTPAs, the APC payment level for the five clinic visit APCs would be set at 175 percent of the Medicare APC level, while the five ER visit APCs would be increased by 200 percent in the first year of OPPS implementation. In the second year, the APC payment levels would be set at 150 percent of the Medicare APC level for clinic visits and 175 percent for ER APCs. In the third year, the APC visit amounts would be set at 130 percent of the Medicare APC level for clinic visits and 150 percent for ER APCs. In the fourth year, the APC visit amounts would be set at 115 percent of the Medicare APC level for clinic visits and 130 percent for ER APCs. In the fifth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

(*2*) *For non-network hospitals.* Under the TTPAs, the APC payment level for the five clinic and ER visit APCs would be set at 140 percent of the Medicare APC level in the first year of OPPS implementation. In the second year, the APC payment levels would be set at 125 percent of the Medicare APC level for clinic and ER visits. In the third year, the APC visit amounts would be set at 110 percent of the Medicare APC level for clinic and ER visits. In the fourth year, the TRICARE and Medicare payment levels for the 10 APC visit codes would be identical.

(*3*) An additional temporary military contingency payment adjustment (TMCPA) will also be available at the discretion of the Director, Defense Health Agency (DHA), or a designee, at any time after implementation to adopt, modify and/or extend temporary adjustments to OPPS payments for TRICARE network hospitals deemed essential for military readiness and deployment in time of contingency operations. Any TMCPAs to OPPS payments shall be made only on the basis of a determination that it is impracticable to support military readiness or contingency operations by making OPPS payments in accordance with the same reimbursement rules implemented by Medicare. The criteria for adopting, modifying, and/or extending deviations and/or adjustments to OPPS payments shall be issued through TRICARE policies, instructions, procedures and guidelines as deemed appropriate by the Director, DHA, or a designee. TMCPAs may also be extended to non-network hospitals on a case-by-case basis for specific procedures where it is determined that the procedures cannot be obtained timely enough from a network hospital. For such case-by-case extensions, ''Temporary'' might be less than three years at the discretion of the DHA Director, or designee.

* * * * *

(j) * * *

(1) * * *

(xi) *Pharmaceutical agents utilized as part of medically necessary medical services.* In general, the TRICARE-determined allowed amount shall be equal to an amount determined to be appropriate, to the extent practicable, in accordance with the same reimbursement rules as apply to payments for similar services under Medicare. Under the authority of 10 U.S.C. 1079(q), in the case of any pharmaceutical agent utilized as part of medically necessary medical services, the Director may adopt special reimbursement methods, amounts, and procedures to encourage the use of high-value products and discourage the use of low-value products, as determined by the Director. For this purpose, the Director may obtain recommendations from the Pharmaceutical and Therapeutics Committee under § 199.21 or other entities as the Director, DHA deems appropriate with respect to the relative value of products in a class of products subject to this paragraph. Among the special reimbursement methods the Director may choose to adopt under this paragraph is to reimburse the average sales price of a product plus a percentage of the median of the average sales prices of products in the product class or category. The Director shall issue guidance regarding the special reimbursement methods adopted and the appropriate reimbursement rates.

* * * * *

■ 3. Section 199.21 is amended by adding paragraph (e)(3), and by revising paragraphs (i)(2)(ii), (iv), and (x), to read as follows:

§ 199.21 TRICARE Pharmacy Benefits Program.

* * * * *

(e) * * *

(3) *Special rules for best clinical effectiveness.* (i) Under the authority of 10 U.S.C. 1074g(a)(10), the Pharmacy and Therapeutics Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Such special actions may operate as exceptions to the normal rules and procedures under 10 U.S.C. 1074g(a)(2), (5) and (6) and the related provisions of this section.

(ii) Actions under paragraph (e)(3)(i) of this section may include a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD. A partial exclusion under this paragraph may take the form (as one example) of a limitation on the clinical conditions, diagnoses, or indications for which the pharmaceutical agent may be prescribed. A partial exclusion may be implemented through any means recommended by the Pharmacy and Therapeutics Committee, including but not limited to preauthorization under paragraph (k) of this section. In the case of a partial exclusion, a pharmaceutical agent may be available on the non-formulary tier of the uniform formulary for limited purposes and for other purposes be excluded.

(iii) Actions under paragraph (e)(3)(i) of this section may also include giving preferential status to any non-generic pharmaceutical agent of the uniform formulary by treating it for purposes of cost-sharing as a generic product.

* * * * *

(i) * * *

(2) * * *

(ii) For pharmaceutical agents obtained from a retail network pharmacy, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a $0 cost-share for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

* * * * *

(iv) For pharmaceutical agents obtained under the TRICARE mail order program, the cost share will be as provided in 10 U.S.C. 1074g(a)(6), except that there is a $0 cost-share for smoking cessation pharmaceutical agents covered under the smoking cessation program.

* * * * *

(x) For any year after 2027, the cost-sharing amounts under this paragraph shall be equal to the cost-sharing amounts for the previous year adjusted by an amount, if any, determined by the Director to reflect changes in the costs of pharmaceutical agents and prescription dispensing, rounded to the nearest dollar. These cost changes, if any, will consider costs under the

TRICARE pharmacy benefits program calculated separately for each of the following categories based on prescriptions filled in the most recent period for which TRICARE cost data are available, updated to the current year, if necessary, by appropriate industry data:

(A) Generic drugs in the retail point of service;

(B) Formulary drugs in the retail point of service;

(C) Generic drugs in the mail order point of service;

(D) Formulary drugs in the mail order point of service;

(E) Non-formulary drugs.

* * * * *

Dated: December 3, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–26562 Filed 12–10–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2018–1052]

Safety Zone; Menominee River, Marinette, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone on the Menominee River in Marinette WI on December 15, 2018 from 10 a.m. to 12 p.m. This action is necessary and intended to protect the safety of life and property on navigable waterways before, during and after the launch of a naval vessel from Marinette Marine on the Menominee River in Marinette, WI. During the enforcement period, the Coast Guard will enforce restrictions upon, and control movement of, vessels in the safety zone. No person or vessel may enter into, transit, or anchor within the safety zone while it is being enforced unless authorized by the Captain of the Port Lake Michigan or a designated representative.

DATES: The regulations in 33 CFR 165.929 will be enforced for safety zone (f)(13), Table 165.929, from 10 a.m. through 12 p.m. on December 15, 2018.

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

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Operations at Marinette Marine Safety Zone listed as item (f)(13) in Table 165.929 of 33 CFR 165.929 on December 15, 2018 from 10 a.m. to 12 p.m. This action is being taken to protect the safety of life and property on navigable waterways of the Menominee River, WI.

The safety zone will encompass all waters of the Menominee river in the vicinity of Marinette Marine Corporation, from the Bridge Street Bridge located in position 45°06.188′ n, 087°37.583′ w, then approximately .95 nm south east to a line crossing the river perpendicularly passing through positions 45°05.881′ n, 087°36.281′ w and 45°05.725′ n, 087°36.385′ w (NAD 83). As specified in 33 CFR 165.929, all vessels must obtain permission from the Captain of the Port Lake Michigan or a designated representative to enter, move within or exit the safety zone while it is enforced. Vessels or persons granted permission to enter the safety zone must obey all lawful orders or directions of the Captain of the Port Lake Michigan or a designated representative.

This notice of enforcement is issued under authority of 33 CFR 165.929; Safety Zones; Annual events requiring safety zones in the Captain of the Port Lake Michigan zone, and 5 U.S.C. 552(a). In addition to this publication in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification for the enforcement of this zone via Broadcast Notice to Mariners or Local Notice to Mariners.

The Captain of the Port Lake Michigan or a designated representative will inform the public through a Broadcast Notice to Mariners of any changes in the planned schedule. The Captain of the Port Lake Michigan or a representative may be contacted via Channel 16, VHF–FM or at (414) 747–7182

Dated: November 27, 2018.

Thomas J. Stuhlreyer

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan .

[FR Doc. 2018–26719 Filed 12–10–18; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

Change Address Quality Threshold for Intelligent Mail Package Barcode

AGENCY: Postal Service™.

ACTION: Interim final rule with request for comments.

SUMMARY: The Postal Service is revising *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) section 204.2.1.8 to update the Address Quality (AQ) Compliance threshold for all mailers who enter commercial parcels.

DATES: *Effective date:* January 31, 2019.

Comment deadline: Comments must be received on or before December 31, 2018.

ADDRESSES: Mail or deliver written comments to the manager, Product Classification, U.S. Postal Service®, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–5015. If sending comments by email, include the name and address of the commenter and send to *ProductClassification@usps.gov,* with a subject line of ''Change Address Quality-IMpb.'' Faxed comments are not accepted. You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC, 20260. These records are available for review on Monday through Friday, 9 a.m.–4 p.m., by calling 202–268–2906.

FOR FURTHER INFORMATION CONTACT: Malaki Gravely at (202) 268–7553 or *Malaki.l.gravely@usps.gov.*

SUPPLEMENTARY INFORMATION: The Postal Service will increase the IMpb® Address Quality (AQ) threshold from 89 percent to 90 percent. The effective date of the new IMpb Address Quality threshold will coincide with the effective date for the previously determined threshold increases for Manifest Quality (MQ) and Barcode Quality (BQ).

Background

On February 27, 2018, the Postal Service published a proposed rule, **Federal Register** Notice (83 FR 8399) *Proposed Changes to Validations for IMpb* to announce its proposal to add new IMpb compliance validations for Barcode Quality (BQ), Address Quality (AQ), and (Shipping Services File) Manifest Quality (MQ) metrics. The proposed rule also reflected IMpb threshold increases for Barcode Quality and (Shipping Services File) Manifest Quality. In addition, the Postal Service provided notice to work in partnership

with the mailing industry to determine the percentage increase for Address Quality threshold.

On September 21, 2018, the Postal Service published a final rule, **Federal Register** Notice (83 FR 47839) *Changes to Validations for IMpb* to amend mailing standards, to add new IMpb compliance quality validations and thresholds for Address Quality, Barcode Quality, and (Shipping Services File) Manifest Quality.

Additional time was needed to discuss the validation requirements for Address Quality before increasing the AQ threshold. The Postal Service and mailing industry have agreed on 90% as the new AQ threshold. The new AQ threshold is effective January 31, 2019, and the assessment of the IMpb Noncompliance Fee pursuant to this new AQ threshold will begin on February 1, 2019. Additionally, the Address Quality (AQ) validation ''*valid primary street number*'' will be removed from the measurement.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations.* See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

200 Commercial Mail

* * * * *

204 Barcode Standards

* * * * *

2.0 Standards for Package and Extra Service Barcodes

2.1 Intelligent Mail Package Barcode

* * * * *

2.1.8 Compliance Quality Thresholds

[Add a new second sentence and revise the last sentence in 2.1.8 to read as follows:]

* * * Failure to meet any compliance quality threshold in Exhibit 2.1.8 will result in the assessment of the IMpb Noncompliance Fee. For details, see Publication 199: *Intelligent Mail Package Barcode (IMpb) Implementation Guide for: Confirmation Services and Electronic Verification System (eVS) Mailers,* available on PostalPro at *http://postalpro.usps.com.*

EXHIBIT 2.1.8—IMPB COMPLIANCE QUALITY THRESHOLDS

[Revise the ''*Compliance Threshold*'' *for the* ''*Address Quality*'' *line item to read* ''*90*''*; and* ''*Validations*'' *for the* ''*Address Quality*'' *to remove* ''*valid primary street number line.]*

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

Brittany M. Johnson,

Attorney, Federal Compliance.

[FR Doc. 2018–26665 Filed 12–10–18; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0022; FRL–9987–60–Region 10]

Air Plan Approval; Oregon; Removal of Obsolete Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the removal of outdated rules in the Code of Federal Regulations (CFR) for the State of Oregon because they are duplicative or obsolete. Removal of such material from the air program subparts is designed to improve cost effectiveness and usability of the CFR. The EPA is also approving non-substantive revisions to reflect updated citations and correcting a typographical error. This final action makes no substantive changes to the Oregon State Implementation Plan and imposes no new requirements.

DATES: This action is effective on January 10, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R10–OAR–2018–0022. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Christi Duboiski, EPA Region 10, at (360) 753–9081, or *duboiski.christi@epa.gov*.

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

I. Background

This action is being taken pursuant to Executive Order 13563—*Improving Regulation and Regulatory Review*. It is intended to reduce the number of pages in the Code of Federal Regulations (CFR) by identifying those rules in 40 CFR part 52, subpart MM, for the State of Oregon that are duplicative or obsolete. This action removes historical information and rules that no longer have any use or legal effect because they have been superseded by subsequently approved state implementation plan (SIP) revisions or they are no longer necessary because the EPA previously promulgated administrative rule actions to replace these sections with summary tables in 40 CFR 52.1970 (78 FR 74012, December 10, 2013). On October 10, 2010, the EPA proposed to approve these changes and received no comments on our proposed rulemaking (83 FR 50867).

II. Final Action

This final action is a ''housekeeping'' exercise that removes duplicative or obsolete CFR provisions and corrects a non-substantive typographical error. The EPA is approving the removal of 40 CFR 52.1973, 40 CFR 52.1974 paragraphs (b) and (c), 40 CFR 52.1977, and 40 CFR 52.1982; and approving the amendment to 40 CFR 52.1974(a). The EPA is removing the duplicative or obsolete rules because they have been revised or superseded by subsequently approved SIP revisions. These actions make no substantive changes to the SIP. The changes will be accurately reflected in 40 CFR part 52, subpart MM for the State of Oregon.

III. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive 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 the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the 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 February 11, 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: November 19, 2018.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

For the reasons set forth in the preamble, 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 MM—Oregon

§ 52.1973 [Removed and Reserved]

■ 2. Section 52.1973 is removed and reserved.

■ 3. Section 52.1974 is revised to read as follows:

§ 52.1974 Original identification of plan section.

(a) This section identified the original ''State of Oregon Clean Air Act Implementation Plan'' and all revisions submitted by Oregon that were federally approved prior to July 1, 2013. The information in this section is available in the 40 CFR, part 52, Volume 4 (§ 52.1970 to End) edition revised as of July 1, 2013.

(b)–(c) [Reserved]

§§ 52.1977 and 52.1982 [Removed and Reserved]

■ 4. Sections 52.1977 and 52.1982 are removed and reserved.

■ 5. In § 52.1988, paragraph (a) is revised to read as follows:

§ 52.1988 Air contaminant discharge permits.

(a) Except for compliance schedules under OAR 340–200–0050, emission limitations and other provisions contained in Air Contaminant Discharge Permits issued by the State in accordance with the provisions of the Federally-approved rules for Air Contaminant Discharge Permits (OAR chapter 340, Division 216), Plant Site Emission Limit (OAR chapter 340, Division 222), Alternative Emission Controls (OAR 340–226–0400) and Public Participation (OAR chapter 340, Division 209), shall be applicable requirements of the Federally-approved Oregon SIP (in addition to any other provisions) for the purposes of section 113 of the Clean Air Act and shall be enforceable by EPA and by any person in the same manner as other requirements of the SIP. Plant site emission limits and alternative emission limits (bubbles) established in Federal Operating Permits issued by the State in accordance with the Federally-approved rules for Plant Site Emission Limit (OAR chapter 340, Division 222) and Alternative Emission Controls (OAR 340–226–0400), shall be applicable requirements of the Federally-approved Oregon SIP (in addition to any other

provisions) for the purposes of section 113 of the Clean Air Act and shall be enforceable by EPA and by any person in the same manner as other requirements of the SIP.

* * * * *

[FR Doc. 2018–26688 Filed 12–10–18; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 36

[WC Docket No. 14–130, CC Docket No. 80–286; FCC 18–141]

Comprehensive Review of the Uniform System of Accounts; Jurisdictional Separations and Referral to the Federal-State Joint Board

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission simplifies its jurisdictional separations rules, applying the separations processes previously reserved for smaller carriers to all carriers subject to those rules, and harmonizing the jurisdictional separations rules with the accounting rules. With this action, the Commission continues to modernize existing rules and eliminate outdated compliance requirements.

DATES: *Effective date:* January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Christopher Koves, Pricing Policy Division, Wireline Competition Bureau at 202–418–8209 or by email at *Christopher.Koves@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, WC Docket No. 14–130, CC Docket No. 80–286; FCC 18–141, adopted on October 16, 2018, and released on October 17, 2018. A full-text version of this document can be obtained at the following internet address: *https://www.fcc.gov/document/fcc-harmonizes-separations-rules-revised-accounting-rules.*

Synopsis

I. Introduction

1. In this Report and Order (Order), the Commission simplifies its part 36 jurisdictional separations rules to allow all carriers to use the simpler jurisdictional separations processes previously reserved for smaller carriers. In so doing, the Commission harmonizes its part 36 rules with the Commission's previous amendments to its part 32 accounting rules. The amendments the Commission adopts today to its part 36 rules further its goal of updating and modernizing its rules to eliminate outdated compliance burdens on carriers so that they can focus their resources on building modern networks that bring economic opportunity, job creation, and civic engagement to all Americans.

II. Background

2. Jurisdictional separations is the third step in a four-step regulatory process. First, a rate-of-return carrier records its costs and revenues in various accounts using the Uniform System of Accounts (USOA) prescribed by the Commission's part 32 rules. Second, the carrier divides the costs and revenues in these accounts between regulated and nonregulated activities in accordance with part 64 of the Commission's rules, a step that helps ensure that the costs of nonregulated activities will not be recovered through regulated interstate rates. Third, the carrier separates the regulated costs and revenues between the intrastate and interstate jurisdictions using the part 36 rules. Finally, the carrier apportions the interstate regulated costs among the interexchange services and rate elements that form the cost basis for its exchange access tariff. Carriers subject to rate-of-return regulation perform this apportionment in accordance with the Commission's part 69 rules.

3. Historically, the part 32 rules divided incumbent local exchange carriers (LECs) into two classes for accounting purposes based on the amounts of their annual regulated revenues. Class A incumbent LECs were the larger carriers, and Class B incumbent LECs were the smaller carriers (most recently those with less than $157 million in annual regulated revenues). The Commission's former part 32 rules required Class A carriers to create and maintain a more granular set of accounts than it required of the smaller Class B carriers. In all but one case, Class A carrier accounts could be grouped into sets that were represented by single Class B carrier accounts—that is, such Class A accounts consolidated into, or ''rolled up'' into, Class B accounts.

4. In the *Part 32 Reform Order,* 82 FR 20833, May 4, 2017, the Commission eliminated the historical distinction between Class A and Class B incumbent LECs in the part 32 rules. Now all carriers subject to part 32 are required to keep only the less onerous accounts previously kept by Class B incumbent LECs. Recognizing that the part 32 accounting reforms had implications for the part 36 jurisdictional separations rules, which distinguish between Class A and Class B incumbent LECs, the Commission referred to the Federal-State Joint Board on Jurisdictional Separations (Joint Board) consideration of how and when the part 36 rules should be modified to reflect the reforms adopted in the *Part 32 Reform Order.*

5. In October 2017, after seeking public comment on how best to harmonize the part 32 and part 36 rules, the Joint Board released a *Recommended Decision.* In its *Recommended Decision,* the Joint Board recommended changes to part 36 including deleting rules pertaining to Class A accounts, deleting references to Class A and B accounts, and allowing former Class A carriers to select between the former Class A and B procedures for apportioning general support facilities costs. The Joint Board also recommended that the Commission make certain stylistic and typographical corrections to the part 36 rules. The Joint Board recommended that the part 36 revisions it proposed be effective as soon as practicable after January 1, 2018, the effective date of the *Part 32 Reform Order.*

6. In February 2018, the Commission released the *Separations Harmonization NPRM,* 83 FR 10817, March 13, 2018, which proposed amendments to part 36 consistent with the *Recommended Decision.* The Commission also sought comment on the effective date for any changes to part 36 to harmonize those rules with part 32 reforms. USTelecom filed the only comment on the merits, and it supports the proposals in the *Separations Harmonization NPRM.*

III. Discussion

7. In this Order, the Commission harmonizes its part 36 jurisdictional separations rules with the changes to the part 32 accounting rules that the Commission adopted in the *Part 32 Reform Order.* The Commission's amendments to part 36 implement the Commission's proposals in the *Separations Harmonization NPRM* to adopt, with minor exceptions, the Joint Board's recommendations and to amend the part 36 rules consistent with those recommendations. The Commission agrees with USTelecom that these rule changes do not risk undermining the primary purpose of the part 36 rules, which is to ''prevent incumbent LECs from recovering the same costs in the interstate and intrastate jurisdictions,'' and will instead ''simplify the accounting rules by removing unnecessary burdensome regulations that require carriers and ultimately consumers to incur unnecessary costs.''

8. First, the Commission removes from its part 36 rules references to Class A accounts because carriers are no longer required to keep such accounts. As the Commission proposed, it: (a) Deletes references to Class A accounts and the phrase ''Class B accounts'' in part 36 rules that contain parallel references to Class A accounts and the Class B accounts into which they roll up; (b) deletes references to current-year account balances and modify references to Class A carriers in other part 36 rules; and (c) deletes references to Class A accounts in §§ 36.501 and 36.505 of the rules. As USTelecom explains, these revisions are ''necessary clean-up to ensure that both rule parts [*i.e.,* parts 32 and 36] work together consistently'' and further the part 32 reforms by ''removing additional unnecessary and burdensome rules for carriers of all sizes.''

9. Second, the Commission amends § 36.112 to allow former Class A carriers (carriers with revenue equal to or greater than $157 million for calendar year 2016) to select between the legacy Class A and Class B procedures in apportioning their general support facilities costs. As the Commission observed in the *Separations Harmonization NPRM,* this is the only part 36 rule that provides different separations procedures for legacy Class A and B carriers. The Commission agrees with the Joint Board that requiring all carriers to use the method previously used only by Class B carriers would ''impose a compliance burden on current Class A carriers because they would have to change their well-established manner of allocating general support expense.'' The Commission finds that both procedures provide reasonable methods for separating general support facilities costs and allowing legacy Class A carriers to select between these procedures will simplify compliance for carriers while having, at most, a de minimis effect on separations results. The Commission also agrees with USTelecom that it is reasonable to allow carriers the ''flexibility'' to ''adjust their selection[s] as their business needs change'' over time. Accordingly, the Commission allows legacy Class A carriers to choose between the procedures previously identified as Class A or Class B procedures in apportioning their general support facilities costs, and to adjust their selection when they chose to do so.

10. Third, consistent with the Joint Board's recommendation and the Commission's proposals, the Commission corrects certain stylistic and typographical errors in part 36. As USTelecom explains, these ministerial corrections make the separations rules clearer.

11. The Commission agrees with the Joint Board that its proposed revisions to part 36 should ''become effective as soon as practicable'' and with USTelecom's argument that adopting the Commission's proposed harmonizing changes to part 36 ''as soon as possible'' avoids potentially ''confusing'' and ''contradictory'' rules. The Commission also agrees with USTelecom that January 1, 2019 is the earliest practicable effective date for these changes, because it corresponds with the carriers' practices of keeping their USOA accounts on a calendar year basis and using their USOA accounting results for regulatory purposes. The Commission therefore selects January 1, 2019 as the effective date of the rule changes it is adopting.

IV. Procedural Matters

12. *Paperwork Reduction Act Analysis.* This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198.

13. *Congressional Review Act.* The Commission will send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

14. *Final Regulatory Flexibility Act Analysis.* The Regulatory Flexibility Act of 1980 (RFA) requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) concerning the possible impact of the rule changes contained in the Report and Order on small entities.

V. Final Regulatory Flexibility Analysis

15. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Final Regulatory Flexibility Analysis (FRFA) on the possible significant economic impact on small entities by this Report and Order (Order). An Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the Notice of Proposed Rulemaking, 83 FR 10817 (*Separations Harmonization NPRM*). The Commission sought written public comment on the proposals in the *Separations Harmonization NPRM,* including comment on the IRFA. The Commission did not receive comments on the IRFA.

A. Need for, and Objectives of, the Order

16. In this Report and Order (Order), the Commission amends its part 36 jurisdictional separations rules to harmonize them with the Commission's reforms to reduce and eliminate unnecessary or outdated part 32 accounting rules. Jurisdictional separations are the third step in a four-step regulatory process used to establish tariffed rates for interstate and intrastate regulated services for incumbent local exchange carriers (LECs). Carriers first record costs into various part 32 accounts, which they then apportion into regulated and nonregulated costs pursuant to part 64, and further separate the regulated costs between intrastate and interstate jurisdictions pursuant to part 36.

17. In the *Part 32 Reform Order,* the Commission amended its part 32 Uniform System of Accounts (USOA) to streamline or eliminate unnecessary or outdated accounting rules. Recognizing that part 32 reforms implicated part 36, the Commission asked the Federal-State Joint Board on Jurisdictional Separations (Joint Board) to prepare a recommended decision regarding the extent part 36 should be modified in light of the part 32 reforms. The Joint Board released its *Recommended Decision* in October 2017. In the *Separations Harmonization NPRM,* the Commission proposed and sought comment on adoption, with certain minor exceptions, of the Joint Board's recommendations and on amendments to part 36 consistent with those recommendations.

18. The purpose of the part 36 amendments adopted in this Order are to ensure that part 36 is consistent with the part 32 reforms adopted in the *Part 32 Reform Order.* First, this Order removes unnecessary or outdated part 36 references to part 32 accounts that were eliminated by the *Part 32 Reform Order.* Second, this Order gives carriers the flexibility to select between two procedures for apportioning their general support facilities costs. Third, this Order makes certain stylistic and typographical corrections to part 36. Finally, the part 36 amendments adopted in this Order will take effect on January 1, 2019.

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

19. There were no comments that specifically addressed the proposed rules and policies presented in the *Separations Harmonization NPRM* IRFA.

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

20. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments. The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

D. Description and Estimate of the Number of Small Entities To Which Rules May Apply

21. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). Nationwide, there are a total of approximately 27.9 million small businesses, according to the SBA.

22. *Incumbent Local Exchange Carriers.* The rules adopted in this Order affect the tariffed rates for interstate and intrastate regulated services for incumbent local exchange carriers (LECs). Neither the Commission nor the SBA has developed a small business size standard specifically for providers of incumbent local exchange services. The closest applicable size standard under the SBA rules is for Wired Telecommunications Carriers. Under the SBA definition, a carrier is small if it has 1,500 or fewer employees. According to the FCC's Telephone Trends Report data, 1,307 incumbent local exchange carriers (LECs) reported that they were engaged in the provision of local exchange services. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most incumbent LECs are small entities that may be affected by the rules and policies adopted herein.

23. The Commission has included small incumbent LECs in this RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. Because its proposals concerning the part 36 rules will affect all incumbent LECs, some entities employing 1,500 or fewer employees may be affected by the rule changes adopted in this Order. The Commission has therefore included small incumbent LECs in this RFA analysis, although the Commission emphasizes that this RFA action has no effect on the Commission's analyses and determinations in other, non-RFA contexts. The Order adopts changes to part 36 that should result in reduced regulatory burdens on incumbent LECs. The Commission notes, however, that the reforms adopted in this Order are focused on incumbent LECs with regulated annual revenues equal to or above $157 million, a group that likely excludes many small incumbent LECs.

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

24. None.

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

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

26. As discussed above, the purpose of this Order is to ensure that the part 36 rules are consistent with the amendments to the part 32 rules adopted in the *Part 32 Reform Order.* In the *Separations Harmonization NPRM,* the Commission sought comment on the effects its part 36 proposals would have on small entities, and whether any rules adopted should apply differently to small entities. The Commission requested that commenters consider the costs and burdens of possible rule amendments on small incumbent LECs and whether such amendments would disproportionately affect specific types of carriers or ratepayers.

27. The rules adopted in this Order will ease the administrative burden of regulatory compliance for incumbent LECs, including any small incumbent LECs those rules affect. The *Part 32 Reform Order* reduced the number of part 32 accounts that incumbent LECs with regulated annual revenues equal to or above $157 million are required to keep, and the amendments to part 36 adopted in this Order would carry forward those reductions into the jurisdictional separations process. The rules adopted in this Order apply solely to incumbent LECs and result in reduced regulatory burdens. The Commission therefore certifies that this Order will not have a significant impact on small entities.

G. Federal Rules That May Duplicate, Overlap, or Conflict With the Final Rules

28. None.

H. Report to Congress

29. The Commission will send a copy of the Order, including this FRFA, in a report to be sent to Congress and the Government Accountability Office pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Commission will send a copy of the Order, including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.

VI. Ordering Clauses

30. Accordingly, *It is ordered* that, pursuant to the authority contained in sections 1, 2, 4(i) and (j), 201, 205, 220, 221(c), 254, 303(r), 403, and 410 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i) and (j), 201, 205, 220, 221(c), 303(r), 403, 410, this Report and Order IS ADOPTED.

31. *It is further ordered* that, pursuant to the authority contained in sections 1, 2, 4(i) and (j), 201, 205, 220, 221(c), 254, 303(r), 403, and 410 of the

Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i) and (j), 201, 205, 220, 221(c), 254, 303(r), 403, 410, part 36 of the Commission's rules, 47 CFR part 36, *Is amended*, and such rule amendments *shall be effective* on January 1, 2019.

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

33. *It is further ordered* that the Commission SHALL SEND a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act.

List of Subjects in 47 CFR Part 36

Communications common carriers, Reporting and recordkeeping requirements, Telephone, Uniform System of Accounts.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 36 as follows:

PART 36—JURISDICTIONAL SEPARATIONS PROCEDURES; STANDARD PROCEDURES FOR SEPARATING TELECOMMUNICATIONS PROPERTY COSTS, REVENUES, EXPENSES, TAXES AND RESERVES FOR TELECOMMUNICATIONS COMPANIES

■ 1. The authority citation for part 36 is revised to read as follows:

Authority: 47 U.S.C. 151, 152, 154(i) and (j), 201, 205, 220, 221(c), 254, 303(r), 403, 410, and 1302 unless otherwise noted.

■ 2. Revise § 36.112 to read as follows:

§ 36.112 Apportionment procedure.

(a) The costs of the general support facilities of local exchange carriers that had annual revenues from regulated telecommunications operations equal to or greater than $157 million for calendar year 2016 are apportioned among the operations on the basis of either the method in paragraph (a)(1) of this section or the method in paragraph (a)(2) of this section, at the election of the local exchange carrier:

(1) The separation of the costs of the combined Big Three Expenses which include the following accounts:

TABLE 1 TO PARAGRAPH (a)(1)

Plant Specific Expenses	
Central Office Switching Expenses	Account 6210.
Operators Systems Expenses	Account 6220.
Central Office Transmission Expenses	Account 6230.
Information Origination/Termination Expenses	Account 6310.
Cable and Wire Facilities Expenses	Account 6410.
Plant Non-Specific Expenses	
Network Operations Expenses	Account 6530.
Customer Operations Expenses	
Marketing	Account 6610.
Services	Account 6620.

(2) The separation of the costs of Central Office Equipment, Information Origination/Termination Equipment, and Cable and Wire Facilities, combined.

(b) The costs of the general support facilities of local exchange carriers that had annual revenues from regulated telecommunications operations less than $157 million for calendar year 2016 are apportioned among the operations on the basis of the separation of the costs of Central Office Equipment, Information Origination/Termination Equipment, and Cable and Wire Facilities, combined.

■ 3. Amend § 36.121 by revising the table in paragraph (a) and the first sentence in paragraph (c)(1)(i) to read as follows:

§ 36.121 General.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Central Office Switching	Account 2210.
Operator Systems	Account 2220.
Central Office Transmission	Account 2230.

* * * * *

(c) * * *

(1) * * *

(i) The cost of power equipment used by one category is assigned directly to that category, *e.g.,* 130-volt power supply provided for circuit equipment. * * *

* * * * *

■ 4. Amend § 36.124 by revising the first sentence in paragraph (a) and paragraph (c) to read as follows:

§ 36.124 Tandem switching equipment—Category 2.

(a) Tandem switching equipment is contained in Account 2210. * * *

* * * * *

(c) Effective July 1, 2001, through December 31, 2018, study areas subject

to price cap regulation, pursuant to § 61.41 of this chapter, shall assign the average balance of Account 2210 to Category 2, Tandem Switching Equipment based on the relative percentage assignment of the average balance of Account 2210 (or, if Accounts 2211, 2212, and 2215 were required to be maintained at the applicable time, the average balances of Accounts 2211, 2212, and 2215) to Category 2, Tandem Switching Equipment during the twelve-month period ending December 31, 2000.

* * * * *

§ 36.125 [Amended]

■ 5. Amend § 36.125 as follows:
■ a. In the introductory text of paragraph (a):
■ i. Remove ''accounts 2210, 2211, and 2212'' and add in its place ''account 2210''; and
■ ii. Add a comma before ''transmitters,'' after ''directors'', and before ''switching equipment, TWX''.
■ b. In paragraph (h):
■ i. Remove the reference to ''balances of Accounts 2210, 2211, and 2212'' and add in its place ''balance of Account 2210''; and
■ ii. Remove the reference to ''balances of Account 2210, 2211, 2212 and 2215'' and add in its place ''balance of Account 2210 (or, if Accounts 2211, 2212, and 2215 were required to be maintained at the applicable time, the average balances of Accounts 2211, 2212, and 2215)''.

§ 36.126 [Amended]

■ 6. Amend § 36.126 as follows:
■ a. In the introductory text of paragraph (a), remove ''Accounts 2230 through 2232 respectively'' and add in its place ''Account 2230''.
■ b. In the introductory text of paragraph (b), remove the word ''equiment'' and add in its place ''equipment''.
■ c. In paragraphs (b)(5) and (6):
■ i. Remove the first reference to ''balances of Accounts 2230 through 2232'' and add in its place ''balance of Account 2230''; and
■ ii. Remove the second reference to ''balances of Accounts 2230 through 2232'' and add in its place ''balance of Account 2230 (or, if Accounts 2231 and 2232 were required to be maintained at the applicable time, the average balances of Accounts 2231 and 2232)''.

§ 36.154 [Amended]

■ 7. Amend § 36.154(b) by removing the word ''jurisdication'' and adding in its place ''jurisdiction''.

§ 36.201 [Amended]

■ 8. Amend § 36.201 by:
■ a. Redesignating paragraph (a) as undesignated introductory text; and
■ b. In the table, removing ''(Class B telephone companies); Basic area revenue—Account 5001 (Class A telephone companies)''.

§ 36.211 [Amended]

■ 9. Amend § 36.211 by:
■ a. Redesignating paragraph (a) as undesignated introductory text; and
■ b. In the table:
■ i. Removing ''Basic local service revenue (Class B telephone companies)'' and adding ''Basic Local Service Revenue'' in its place; and
■ ii. Removing the entry for ''Basic Area Revenue (Class A telephone companies)''.

■ 10. Amend § 36.212 by revising the section heading to read as follows:

§ 36.212 Basic local services revenue—Account 5000.

* * * * *

■ 11. Amend § 36.301 by:
■ a. Redesignating paragraph (a) as undesignated introductory text; and
■ b. In the table:
■ i. Removing the entry ''Network Support/General Support Expenses—Accounts 6110 and 6120 (Class B Telephone Companies); Accounts 6112, 6113, 6114, 6121, 6122, 6123, and 6124 (Class A Telephone Companies)'' and adding an entry for ''Network Support/General Support Expenses—Accounts 6110 and 6120'' in its place;
■ ii. Removing the entry ''Central Office Expenses—Accounts 6210, 6220, 6230 (Class B Telephone Companies); Accounts 6211, 6212, 6220, 6231, and 6232 (Class A Telephone Companies)'' and adding an entry for ''Central Office Expenses—Accounts 6210, 6220, 6230'' in its place;
■ iii. Removing the entry ''Information Origination/Termination Expenses—Account 6310 (Class B Telephone Companies); Accounts 6311, 6341, 6351, and 6362 (Class A Telephone Companies)'' and adding an entry for ''Information Origination/Termination Expenses—Account 6310'' in its place;
■ iv. Removing the entry ''Cable and Wire Facilities Expenses—Account 6410 (Class B Telephone Companies); Accounts 6411, 6421, 6422, 6423, 6424, 6426, 6431, and 6441 (Class A Telephone Companies)'' and adding an entry for ''Cable and Wire Facilities Expenses—Account 6410'' in its place;
■ v. Removing the entry ''Other Property Plant and Equipment Expenses—Account 6510 (Class B Telephone Companies); Accounts 6511 and 6512 (Class A Telephone Companies)'' and adding an entry for ''Other Property Plant and Equipment Expenses—Account 6510'' in its place;
■ vi. Removing the entry ''Network Operations Expenses—Account 6530 (Class B Telephone Companies); Accounts 6531, 6532, 6533, 6534, and 6535 (Class A Telephone Companies)'' and adding an entry for ''Network Operations Expenses—Account 6530'' in its place;
■ vii. Removing the entry ''Marketing—Account 6610 (Class B Telephone Companies); Accounts 6611 and 6613 (Class A Telephone Companies)'' and adding an entry for ''Marketing—Account 6610'' in its place; and
■ viii. Removing the entry ''Operating Taxes—Account 7200 (Class B Telephone Companies); Accounts 7210, 7220, 7230, 7240, and 7250 (Class A Telephone Companies)'' and adding an entry for ''Operating Taxes—Account 7200'' in its place.

The additions read as follows:

§ 36.301 Section arrangement.

* * * * * * *	
Plant Specific Operations Expenses:	
* * * * * * *	
Network Support/General Support Expenses—Accounts 6110 and 6120	36.311.
Central Office Expenses—Accounts 6210, 6220, 6230	36.321.
Information Origination/Termination Expenses—Account 6310	36.331.
Cable and Wire Facilities Expenses—Account 6410	36.341.
Plant Nonspecific Operations Expenses:	
* * * * * * *	
Other Property Plant and Equipment Expenses—Account 6510	36.352.
Network Operations Expenses—Account 6530	36.353.

* * * * * * *	
Customer Operations Expenses:	
* * * * * * *	
Marketing—Account 6610	36.372.
* * * * * * *	
Corporate Operations Expenses:	
* * * * * * *	
Operating Taxes—Account 7200	36.411 and 36.412.
* * * * * * *	

■ 12. Amend § 36.302 by revising paragraphs (c)(1) introductory text and (c)(1)(i) to read as follows:

§ 36.302 General.

(c) * * *

(1) Subsidiary Record Categories (SRCs) for Salaries and Wages, Benefits and Other Expenses are applicable to all of the expense accounts except for:

(i) SRCs for access expenses are maintained to identify interstate and state access expense and billing and collection expense for carrier's carrier.

* * * * *

■ 13. Amend § 36.310 by revising the table in paragraph (a) to read as follows:

§ 36.310 General.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Network Support Expenses	Account 6110.
General Support Expenses	Account 6120.
Central Office Switching Expenses	Account 6210.
Operator System Expenses	Account 6220.
Central Office Transmission Expenses	Account 6230.
Information Origination/Termination Expenses	Account 6310.
Cable and Wire Facilities Expenses	Account 6410.

* * * * *

■ 14. Amend § 36.311 by revising the section heading to read as follows:

§ 36.311 Network Support/General Support Expenses—Accounts 6110 and 6120.

* * * * *

■ 15. Amend § 36.321 by revising the section heading, the table in paragraph (a), and paragraph (b) to read as follows:

§ 36.321 Central office expenses—Accounts 6210, 6220, and 6230.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Central Office Switching Expense	Account 6210.
Operator Systems Expense	Account 6220.
Central Office Transmission Expense	Account 6230.

(b) The expenses in these accounts are apportioned among the operations on the basis of the separation of the investments in central office equipment—Accounts 2210, 2220 and 2230, combined.

■ 16. Amend § 36.331 by revising the section heading to read as follows:

§ 36.331 Information origination/termination expenses—Account 6310.

* * * * *

■ 17. Amend § 36.341 by revising the section heading to read as follows:

§ 36.341 Cable and wire facilities expenses—Account 6410.

* * * * *

■ 18. Revise § 36.351 to read as follows:

§ 36.351 General.

Plant nonspecific operations expenses include the following accounts:

TABLE 1 TO § 36.351

Other Property Plant and Equipment Expenses	Account 6510.
Network Operations Expenses	Account 6530.
Access Expenses	Account 6540.
Depreciation and Amortization Expenses	Account 6560.

■ 19. Amend § 36.352 by revising the section heading to read as follows:

§ 36.352 Other property plant and equipment expenses—Account 6510.

* * * * *

■ 20. Amend § 36.353 by revising the section heading to read as follows:

§ 36.353 Network operations expenses—Account 6530.

* * * * *

§ 36.371 [Amended]

■ 21. Amend § 36.371, in the table, by removing ''(Class B telephone companies); Accounts 6611 and 6613 (Class A telephone companies)''.

■ 22. Amend § 36.372 by revising the section heading to read as follows:

§ 36.372 Marketing—Account 6610.

* * * * *

§ 36.375 [Amended]

■ 23. Amend § 36.375(b)(4) and (5) by removing ''through (4)'' and adding in its place ''through (3)''.

§ 36.377 [Amended]

■ 24. Amend § 36.377 by adding a reserved paragraph (b).

■ 25. Amend § 36.392 by revising paragraph (c) to read as follows:

§ 36.392 General and administrative—Account 6720.

* * * * *

(c) The expenses in this account are apportioned among the operations on the basis of the separation of the cost of the combined Big Three Expenses which include the following accounts:

TABLE 1 TO PARAGRAPH (c)

Plant Specific Expenses	
Central Office Switching Expenses	Account 6210.
Operators Systems Expenses	Account 6220.
Central Office Transmission Expenses	Account 6230.
Information Origination/Termination Expenses	Account 6310.
Cable and Wire Facilities Expense	Account 6410.
Plant Non-Specific Expenses	
Network Operations Expenses	Account 6530.
Customer Operations Expenses	
Marketing	Account 6610.
Services	Account 6620.

■ 26. Revise § 36.411 to read as follows:

§ 36.411 Operating taxes—Account 7200.

This account includes the taxes arising from the operations of the company, *i.e.:*

(a) Operating Investment Tax Credits.

(b) Operating Federal Income Taxes.

(c) Operating State and Local Income Taxes.

(d) Operating Other Taxes.

(e) Provision for Deferred Operating Income Taxes.

§ 36.501 [Amended]

■ 27. Amend § 36.501, in the table, by removing ''(Class B Telephone Companies); Account 3410 (Class A Telephone Companies)''.

§ 36.505 [Amended]

■ 28. Amend § 36.505 as follows:

■ a. Revise the section heading; and

■ b. Redesignate paragraph (a) as an undesignated paragraph.

The revision reads as follows:

§ 36.505 Accumulated amortization—Tangible—Account 3400.

* * * * *

§§ 36.3, 36.123, 36.124, 36.125, 36.126, 36.141, 36.142, 36.152, 36.157, 36.191, 36.374, 36.375, 36.377, 36.378, 36.379, 36.380, 36.381, and 36.382 [Amended]

■ 29. In addition to the amendments set forth above, in 47 CFR part 36, remove the words ''twelve month'' and add in their place the words ''twelve-month'' in the following places:

■ a. Section 36.3(a) and (b);

■ b. Section 36.123(a)(5) and (6);

■ c. Section 36.124(d);

■ d. Section 36.125(h) and (i);

■ e. Section 36.126(b)(5) and (6), (c)(4), (e)(4), and (f)(2);

■ f. Section 36.141(c);

■ g. Section 36.142(c);

■ h. Section 36.152(d);

■ i. Section 36.157(b);

■ j. Section 36.191(d);

■ k. Section 36.374(b);

■ l. Section 36.375(b)(4);

■ m. Section 36.377(a) introductory text, (a)(1)(ix), (a)(2)(vii), (a)(3)(vii), (a)(4)(vii), (a)(5)(vii), and (a)(6)(vii);

■ n. Section 36.378(b)(1);

■ o. Section 36.379(b)(1);

■ p. Section 36.380(d) and (e);

■ q. Section 36.381(c); and

■ r. Section 36.382(a).

[FR Doc. 2018–25803 Filed 12–10–18; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 170831849–8404–01]

RIN 0648–XG563

Fisheries Off West Coast States; Modifications of the West Coast Recreational and Commercial Salmon Fisheries; Inseason Actions #12 through #37

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

ACTION: Modification of fishing seasons.

SUMMARY: NMFS announces 26 inseason actions in the ocean salmon fisheries. These inseason actions modified the commercial and recreational salmon fisheries in the area from the U.S./Canada border to the U.S./Mexico border.

DATES: The effective dates for the inseason actions are set out in this document under the heading Inseason Actions.

FOR FURTHER INFORMATION CONTACT: Peggy Mundy at 206–526–4323.

SUPPLEMENTARY INFORMATION:

Background

In the 2018 annual management measures for ocean salmon fisheries (83 FR 19005, May 1, 2018), NMFS announced management measures for the commercial and recreational fisheries in the area from the U.S./Canada border to the U.S./Mexico border, beginning May 1, 2018, through April 30, 2019. NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Pacific Fishery Management Council (Council) and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions). The state management agencies that participated in the consultations described in this document were: California Department of Fish and Wildlife (CDFW), Oregon Department of Fish and Wildlife (ODFW), and Washington Department of Fish and Wildlife (WDFW).

Management Areas

Management of the salmon fisheries is generally divided into two geographic areas: north of Cape Falcon (U.S./Canada border to Cape Falcon, OR) and south of Cape Falcon (Cape Falcon, OR, to the U.S./Mexico border). Within the north and south of Cape Falcon areas, there are further subarea divisions used to manage impacts on salmon stocks or stock groups as well as economic impacts to communities. The management areas affected by the inseason actions in this document are described here.

North of Cape Falcon: Recreational fisheries north of Cape Falcon are divided into four subareas: U.S./Canada border to Cape Alava, WA (Neah Bay subarea), Cape Alava, WA, to Queets River, WA (La Push subarea), Queets River, WA, to Leadbetter Point, WA (Westport subarea), and Leadbetter Point, WA, to Cape Falcon, OR (Columbia River subarea). Commercial fisheries north of Cape Falcon are divided at Queets River, WA, and Leadbetter Point, WA.

South of Cape Falcon: South of Cape Falcon, the area from Humbug Mountain, OR, to Horse Mountain, CA, is the Klamath Management Zone (KMZ) and is managed in two subareas, Oregon KMZ and California KMZ, divided at the Oregon/California border. The Oregon KMZ is the area from Humbug Mountain, OR, to the Oregon/California border. The California KMZ is the area from the Oregon/California border to Horse Mountain, CA. However, the area from Humboldt South Jetty, CA, to Horse Mountain, CA, has been closed to commercial salmon fishing since 1992.

Inseason Actions

Inseason Action #12

Description of the action: Inseason action #12 adjusted the daily bag limit in the recreational salmon fishery in the Neah Bay subarea to allow retention of two Chinook salmon. Previously, the two salmon per day bag limit in this fishery allowed retention of only one Chinook salmon.

Effective dates: Inseason action #12 took effect on July 14, 2018, and remained in effect until the recreational fishery in the Neah Bay subarea closed for the season under inseason action #24 on August 12, 2018.

Reason and authorization for the action: The purpose of this action was to allow greater access to the available Chinook salmon quota in the recreational fishery. The NMFS West Coast Regional Administrator (RA) considered Chinook and coho salmon landings and fishery effort in the Neah Bay subarea and determined that this inseason action was necessary to meet management objectives set preseason. Inseason modification of recreational bag limits is authorized by 50 CFR 660.409(b)(1)(iii).

Consultation date and participants: Consultation on inseason action #12 occurred on July 12, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #13

Description of the action: Inseason action #13 suspended retention of Pacific halibut caught incidental to the commercial salmon fishery from the U.S./Canada border to the U.S./Mexico border.

Effective dates: Inseason action #13 took effect at 11:59 p.m., July 14, 2018, and remained in effect until superseded by inseason action #15 on July 26, 2018.

Reason and authorization for the action: The purpose of this action was to avoid exceeding the allocation of Pacific halibut allowed to be retained in the commercial salmon fishery. The RA considered Chinook salmon and Pacific halibut landings and fishery effort in the commercial salmon fishery and determined that the fishery was at risk of exceeding the allocation of Pacific halibut if retention continued at the current rate. Retention of Pacific halibut was suspended by inseason action to allow the states to update landings data and determine the amount of Pacific halibut allocation that remained. The annual management measures require NMFS to take inseason action to prohibit retention of Pacific halibut in the commercial salmon fishery if the landings are projected to exceed the preseason allocation (83 FR 19005, May 1, 2018). Modification of the species that may be caught and landed during specific seasons is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #13 occurred on July 13, 2018. Representatives from NMFS, WDFW, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #14

Description of the action: Inseason action #14 adjusted the landing and possession limit for the commercial salmon fishery in the California KMZ from 20 Chinook salmon per day to 40 Chinook salmon per day.

Effective dates: Inseason action #14 took effect on July 20, 2018 and remained in effect through July 31, 2013.

Reason and authorization for the action: The purpose of inseason action #14 was to allow greater access to available Chinook salmon quota for July in the commercial salmon fishery in the California KMZ; this fishery had monthly Chinook salmon quotas from May through August in 2018. The RA considered Chinook salmon landings and fishery effort and determined that inseason action was necessary to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #14 occurred on July 17, 2018. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #15

Description of the action: Inseason action #15 allowed retention of Pacific halibut caught incidental to the commercial salmon fishery to resume from the U.S./Canada border to the U.S./Mexico border with revised landing and possession limits of no more than one Pacific halibut per each three Chinook salmon, except one Pacific halibut could be possessed or landed without meeting

the ratio requirement, and no more than 10 halibut could be possessed or landed per trip.

Effective dates: Inseason action #15 took effect on July 26, 2018, superseding inseason action #13, above. Inseason action #15 remained in effect until superseded by inseason action #22 on August 8, 2018.

Reason and authorization for the action: The purpose of inseason action #15 was to allow access to the remaining allocation of Pacific halibut without exceeding the allocation. The RA considered Pacific halibut and Chinook salmon landings to date and fishery effort and determined that inseason action was needed to meet management objectives set preseason. Modification of the species that may be caught and landed during specific seasons is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #15 occurred on July 24, 2018. Representatives from NMFS, WDFW, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #16

Description of the action: Inseason action #16 adjusted the landing and possession limit in the commercial salmon fishery in the areas from the U.S./Canada border to Queets River, WA, and from Leadbetter Point, WA, to Cape Falcon, OR, from 50 to 75 Chinook salmon per vessel per landing week.

Effective dates: Inseason action #16 took effect on July 26, 2018, and remained in effect until superseded by inseason action #18 on August 2, 2018, which affected the area from the U.S./Canada border to Queets River, and inseason action #31 on August 23, 2018, which affected the area from Leadbetter Point, OR to Cape Falcon, OR.

Reason and authorization for the action: The purpose of inseason action #16 was to allow greater access to available Chinook salmon quota in the commercial salmon fishery. The RA considered Chinook salmon landings to date and fishery effort and determined that inseason action was necessary to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #16 occurred on July 24, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #17

Description of the action: Inseason action #17 transferred quota of 1,000 coho from the commercial salmon fishery in the area north of Cape Falcon, OR, to the recreational fishery in the Neah Bay subarea. This action included the provision that, when the recreational fishery in the Neah Bay subarea closed for the season, any remaining Chinook quota from that fishery would be transferred to the commercial fishery on an impact-neutral basis to complete the trade (see inseason action #28, below).

Effective dates: Inseason action #17 took effect on July 24, 2018, and remained in effect through August 12, 2018, when the recreational fishery in the Neah Bay subarea closed for the season under inseason action #24.

Reason and authorization for the action: The purpose of inseason action #17 was to prolong the recreational salmon season in Neah Bay, which was scheduled preseason to remain open until September 3, 2018, and to utilize available coho and Chinook salmon quota. The RA considered Chinook salmon and coho landings to date and fishery effort and determined that inseason was necessary to keep the recreational fishery in Neah Bay open and meet management objectives set preseason. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas or fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #17 occurred on July 24, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #18

Description of the action: Inseason action #18 adjusted the landing and possession limit in the commercial salmon fishery in the area from the U.S./Canada border to Queets River, WA, from 75 to 50 Chinook salmon per vessel per landing week.

Effective dates: Inseason action #18 took effect August 2, 2018, and remained in effect until superseded by inseason action #30 on August 23, 2018.

Reason and authorization for the action: The purpose of the proposed action was to keep commercial Chinook salmon landings in the affected area within the quota set preseason. The RA considered Chinook salmon landings to date and fishery effort and determined that inseason action was necessary to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #18 occurred on August 1, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #19

Description of the action: Inseason action #19 adjusted the August quota in the commercial salmon fishery in the California KMZ to account for an impact-neutral rollover of unused July quota. The August quota was adjusted from 4,000 Chinook salmon to 9,423 Chinook salmon.

Effective dates: Inseason action #19 took effect on August 2, 2018, and remained in effect through August 31, 2018.

Reason and authorization for the action: The purpose of inseason action #19 was to be consistent with the annual management measures, which state that any remaining portion of a monthly Chinook salmon quota in the commercial salmon fishery in the California KMZ may be transferred inseason on an impact-neutral basis to the next open quota period (83 FR 19005, May 1, 2018). The RA considered Chinook salmon landings to date and the calculations of the Council's Salmon Technical Team (STT) for rolling over quota on an impact-neutral basis for impacts to Sacramento and Klamath River fall-run Chinook salmon stocks, and fifty-fifty tribal/nontribal sharing of Klamath River fall-run Chinook salmon allowable catch. The RA determined inseason action was necessary to meet management objectives set preseason. Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #19 occurred on August 2, 2018. Representatives from NMFS, CDFW, ODFW, and the Council participated in this consultation.

Inseason Action #20

Description of the action: Inseason action #20 adjusted the landing and possession limit in the commercial salmon fishery in the California KMZ from 20 to 50 Chinook per vessel per day.

Effective dates: Inseason action #20 took effect August 3, 2018, and remained in effect through the end of the season on August 31, 2018.

Reason and authorization for the action: The purpose of inseason action #20 was to provide greater access to

available quota. The RA considered catch of Chinook salmon to date and fishery effort, as well as the available quota and limited remaining time for the fishery, which was scheduled to close at the end of August, and determined that inseason action was necessary to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #20 occurred on August 2, 2018. Representatives from NMFS, CDFW, ODFW, and the Council participated in this consultation.

Inseason Action #21

Description of the action: Inseason action #21 adjusted the August quota in the commercial salmon fishery in the Oregon KMZ to account for an impact-neutral rollover of unused July quota. The August quota was adjusted from 500 Chinook salmon to 1,430 Chinook salmon.

Effective dates: Inseason action #21 took effect on August 2, 2018, and remained in effect through the end of the season on August 29, 2018.

Reason and authorization for the action: The purpose of inseason action #21 was to be consistent with the annual management measures, which state that any remaining portion of a monthly Chinook salmon quota in the commercial salmon fishery in the Oregon KMZ may be transferred inseason on an impact neutral basis to the next open quota period (83 FR 19005, May 1, 2018). The RA considered Chinook salmon landings to date and the calculations of the Council's Salmon Technical Team (STT) for rolling over quota on an impact-neutral basis for impacts to Sacramento and Klamath River fall-run Chinook salmon stocks, and fifty-fifty tribal/nontribal sharing of Klamath River fall-run Chinook salmon allowable catch. The RA determined inseason action was necessary to meet management objectives set preseason. Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #20 occurred on August 2, 2018. Representatives from NMFS, CDFW, ODFW, and the Council participated in this consultation.

Inseason Action #22

Description of the action: Inseason action #22 closed retention of Pacific halibut caught incidental to the commercial salmon fishery from the U.S./Canada border to the U.S./Mexico border.

Effective dates: Inseason action #22 took effect on August 8, 2018 and remains in effect until all commercial salmon fisheries conclude for 2018.

Reason and authorization for the action: The purpose of inseason action #22 was to prevent exceeding the 2018 allocation of Pacific halibut to the commercial salmon fishery. The RA considered Pacific halibut and salmon landings to date and fishery effort and determined that there was insufficient Pacific halibut allocation remaining to allow retention to continue and inseason action was required to avoid exceeding the Pacific halibut allocation. The annual management measures require NMFS to take inseason action to prohibit retention of Pacific halibut in the commercial salmon fishery if the landings are projected to exceed the preseason allocation (83 FR 19005, May 1, 2018).

Consultation date and participants: Consultation on inseason action #22 occurred on August 8, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation. NMFS notified CDFW of the action immediately after the consultation.

Inseason Action #23

Description of the action: Inseason action #23 transferred 3,000 coho quota to the recreational salmon fishery in the Columbia River subarea. The coho quota transferred comprised 2,400 coho quota from the commercial salmon fishery in the area north of Cape Falcon, OR, and 600 coho quota from the recreational salmon fishery in the Westport subarea.

Effective dates: Inseason action #23 took effect on August 8, 2018, and remained in effect until reversed by inseason action #27 on August 23, 2018.

Reason and authorization for the action: The purpose of inseason action #23 was to prolong the Columbia River subarea recreational salmon fishery, which was scheduled to remain open through September 3, 2018, but which was exhausting its coho quota. The RA considered coho and Chinook salmon landings to date and fishery effort and determined that inseason action was necessary to meet the management objectives set preseason. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #23 occurred on August 8, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #24

Description of the action: Inseason action #24 closed the recreational salmon fishery in the Neah Bay subarea.

Effective dates: Inseason action #24 took effect on August 12, 2018, and remained in effect through the end of the 2018 ocean salmon season.

Reason and authorization for the action: The purpose inseason action #24 was to prevent exceeding the subarea quota for coho. The RA considered coho and Chinook salmon landings and fishery effort and determined that inseason action was necessary to close the fishery ahead of the scheduled date of September 3, 2018, to avoid exceeding the coho quota for the subarea. Inseason action to modify fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #24 occurred on August 8, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #25

Description of the action: Inseason action #25 closed the recreational salmon fishery in the Columbia River subarea.

Effective dates: Inseason action #25 took effect on August 12, 2018, and remained in effect until superseded by inseason action #34 on September 2, 2018.

Reason and authorization for the action: The purpose inseason action #25 was to prevent exceeding the subarea quota for coho. The RA considered coho and Chinook salmon landings and fishery effort and determined that inseason action was necessary to close the fishery ahead of the scheduled date of September 3, 2018, to avoid exceeding the coho quota for the subarea. Inseason action to modify fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #25 occurred on August 8, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #26

Description of the action: Inseason action #26 adjusted the landing and possession limit in the commercial salmon fishery in the Oregon KMZ from 50 to 80 Chinook salmon per vessel per landing week.

Effective dates: Inseason action #26 took effect on August 13, 2018, and remained in effect until the fishery closed on August 29, 2018.

Reason and authorization for the action: The purpose of inseason action #26 was to provide greater access to available Chinook salmon quota. The RA considered Chinook salmon landings to date and fishing effort and determined that inseason action was necessary to meet management goals set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #26 occurred on August 9, 2018. Representatives from NMFS, ODFW, CDFW, and the Council participated in this consultation.

Inseason Action #27

Description of the action: Inseason action #27 reversed the transfer of coho quota to the recreational salmon fishery in the Columbia River subarea that was implemented under inseason action #23. The coho quota was returned, without adjustment, as follows: 2,400 coho quota to the commercial salmon fishery in the area north of Cape Falcon, OR, and 600 coho quota to the recreational salmon fishery in the Westport subarea.

Effective dates: Inseason action #27 took effect on August 23, 2018, and remained in effect until superseded by inseason action #32 on August 30, 2018.

Reason and authorization for the action: The purpose of inseason action #27 was to reverse the transfer of coho quota that was implemented under inseason action #23. The recreational fishery in the Columbia River subarea closed on August 12, 2018, with an estimated remaining coho quota of 3,558. The RA considered coho landings to date and determined that none of the 2,400 coho quota previously transferred under inseason action #23 was landed in the recreational fishery in the Columbia River subarea prior to the closure of that fishery and that inseason action to return the quota to the fisheries from which it was transferred it was warranted. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #27 occurred on August 23, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #28

Description of the action: Inseason action #28 transferred the remaining Chinook salmon guideline (1,876 Chinook salmon) from the recreational salmon fishery in the Neah Bay subarea, which closed August 12, 2018, under inseason action #24, to the commercial fishery in the area from the U.S./Canada border to the Queets River, WA, to complete the trade agreed to under inseason action #17.

Effective dates: Inseason action #28 took effect on August 23, 2018, and remained in effect until the commercial salmon fisheries north of Cape Falcon, OR, closed on September 19, 2018.

Reason and authorization for the action: The purpose of inseason action #28 was to fulfill the quota trade agreement between the commercial and recreational salmon fisheries that began with inseason action #17. Under that trade agreement, the commercial salmon fishery traded 1,000 coho to the recreational salmon fishery in the Neah Bay subarea with the understanding that, when the Neah Bay recreational fishery closed for the season, any remaining Chinook salmon would be transferred to the commercial fishery. The RA considered the Chinook salmon landings in the recreational salmon fishery in the Neah Bay subarea and determined that the transfer was consistent with the decision made under inseason action #17. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #28 occurred on August 23, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #29

Description of the action: Inseason action #29 adjusted the recreational salmon fishery in the Westport subarea to be open seven days per week (previously, it was open Sunday through Thursday) with a daily bag limit of two salmon, both of which can be Chinook salmon (previously, the daily bag limit was two salmon, only one of which could be a Chinook salmon).

Effective dates: Inseason action #29 took effect on August 24, 2018, and remained in effect until the fishery closed on September 3, 2018.

Reason and authorization for the action: The purpose of inseason action #29 was to allow greater access to available quota. The RA considered Chinook salmon and coho landings to date and fishery effort and determined inseason action to allow more fishing opportunity to access available quota was warranted to meet management objectives set preseason. Inseason action to modify recreational bag limits and fishing days per calendar week is authorized by 50 CFR 660.409(b)(1)(iii).

Consultation date and participants: Consultation on inseason action #29 occurred on August 23, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #30

Description of the action: Inseason action #30 adjusted the landing and possession limit in the commercial salmon fishery from the U.S./Canada border to the Queets River, WA, from 50 to 85 Chinook salmon per vessel per landing week.

Effective dates: Inseason action #30 superseded inseason action #18 on August 23, 2018, and remained in effect until the fishery closed on September 19, 2018.

Reason and authorization for the action: The purpose of inseason action #30 was to allow greater access to available Chinook salmon quota. The RA considered coho and Chinook landings and fishery effort and determined that inseason action to increase the landing and possession limit in the fishery was warranted to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #30 occurred on August 23, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #31

Description of the action: Inseason action #31 adjusted the landing and possession limit in the commercial salmon fishery from Leadbetter Point, WA to Cape Falcon, OR, from 75 to 85 Chinook salmon per vessel per landing week.

Effective dates: Inseason action #31 superseded inseason action #16 on August 23, 2018, and remained in effect until the fishery closed on September 19, 2018.

Reason and authorization for the action: The purpose of inseason action #31 was to allow greater access to available Chinook salmon quota. The RA considered coho and Chinook

landings and fishery effort and determined that inseason action to increase the landing and possession limit in the fishery was warranted to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #31 occurred on August 23, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #32

Description of the action: Inseason action #32 transferred 2,400 coho quota from the commercial salmon fishery in the area north of Cape Falcon to the recreational salmon fishery in the Columbia River subarea.

Effective dates: Inseason action #32 took effect on August 30, 2018, and remained in effect until reversed under inseason action #36 on September 12, 2018.

Reason and authorization for the action: The purpose of inseason action #32 was to provide ample coho quota to support re-opening the recreational fishery in the Columbia River subarea during the Labor Day holiday weekend (see inseason action #34, below). Considering coho and Chinook salmon landings to date in the commercial and recreational fisheries and fishery effort, the RA determined that inseason action to transfer available coho quota from the commercial fishery to the recreational fishery was warranted to support the economic benefit of the fishery dependent community in the Columbia River subarea and consistent with management goals set preseason. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #32 occurred on August 30, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #33

Description of the action: Inseason action #33 adjusted the landing and possession limit in the commercial salmon fishery north of Cape Falcon, OR, from 10 to 25 coho, marked with a healed adipose fin clip, per vessel per landing week.

Effective dates: Inseason action #33 took effect August 30, 2018, and remained in effect until the fishery closed on September 19, 2018.

Reason and authorization for the action: The purpose of inseason action #33 was to allow greater access to available coho quota. Considering coho and Chinook salmon landings and fishery effort, the RA determined that inseason action to increase the landing and possession limit in the fishery was warranted to meet management objectives set preseason. Inseason action to modify limited retention regulations is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #33 occurred on August 30, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #34

Description of the action: Inseason action #34 reopened the recreational salmon fishery in the Columbia River subarea from September 2, 2018 through September 3, 2018.

Effective dates: Inseason action #34 superseded inseason action #25 on September 2, 2018, and remained in effect through September 3, 2018, the closing date of the 2018 recreational salmon fishery north of Cape Falcon, Oregon.

Reason and authorization for the action: The purpose of inseason action #34 was to provide recreational fishing opportunity in the Columbia River subarea during the Labor Day holiday weekend. As described under inseason action #32, above, the RA considered landings to date, fishery effort, and available quota, and determined that inseason action to re-open the recreational fishery in the Columbia River subarea was warranted to provide economic benefit and to be consistent with management objectives set preseason. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #34 occurred on August 30, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #35

Description of the action: Inseason action #35 rolled over remaining coho quota from the recreational mark-selective coho fishery in the area from Cape Falcon, OR, to Humbug Mountain, OR, to the recreational non-mark-selective coho fishery on an impact-neutral basis. This action adjusted the quota in the non-mark-selective coho fishery from 3,500 to 7,600 coho.

Effective dates: Inseason action #35 took effect on September 12, 2018, and remained in effect until the fishery was closed by inseason action #37 on September 21, 2018.

Reason and authorization for the action: The purpose of inseason action was to provide access to available coho quota. The annual management measures (83 FR 19005, May 1, 2018) state that marked coho remaining from the Cape Falcon, OR, to Humbug Mountain, OR, recreational mark-selective coho quota may be transferred inseason to the Cape Falcon, OR, to Humbug Mountain, OR, non-mark-selective recreational fishery if the transfer would not result in exceeding preseason impact expectations on any stocks. The RA considered coho landings and the STT's calculations for the impact-neutral roll-over and determined that inseason action to roll over the coho quota between these fisheries was warranted to meet management objectives set preseason.

Consultation date and participants: Consultation on inseason action #35 occurred on September 12, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #36

Description of the action: Inseason action #36 reversed the transfer of coho quota to the recreational salmon fishery in the Columbia River subarea that was implemented under inseason action #32. The 2,400 coho quota was returned to the commercial salmon fishery in the area north of Cape Falcon, OR, without adjustment.

Effective dates: Inseason action #36 took effect on September 12, 2018, and remained in effect until the commercial salmon fishery north of Cape Falcon, OR, closed on September 19, 2018, as scheduled preseason.

Reason and authorization for the action: The purpose of inseason action #36 was to reverse the transfer of coho quota that was implemented under inseason action #32. The recreational fishery in the Columbia River subarea closed on September 3, 2018, with an estimated remaining coho quota of 2,854. The RA considered coho landings to date and determined that none of the 2,400 coho quota previously transferred under inseason action #32 was landed in the recreational fishery in the Columbia River subarea prior to the closure of that fishery on September 3,

2018, and that inseason action to return the quota to the fisheries from which it was transferred it was warranted. Inseason trades and transfers of quota between commercial and recreational fisheries north of Cape Falcon, OR, are authorized by 50 CFR 660.408(d)(1)(vi). Inseason action to modify quotas is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #36 occurred on September 12, 2018. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #37

Description of the action: Inseason action #37 closed the recreational non-mark-selective coho salmon fishery from Cape Falcon, OR, to Humbug Mountain, OR, due to projected attainment of the available coho quota.

Effective dates: Inseason action #37 took effect on September 21, 2018, and remained in effect through the end of the salmon fishing season.

Reason and authorization for the action: The purpose of inseason action #37 was to prevent exceeding the coho quota in the fishery. The RA considered coho landings and remaining quota and determined inseason action was necessary to stay within the adjusted coho quota. Inseason action to modify fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #37 occurred on September 19, 2018. Representatives from NMFS, ODFW, and the Council participated in this consultation.

All other restrictions and regulations remain in effect as announced for the 2018 ocean salmon fisheries and 2019 salmon fisheries opening prior to May 1, 2019 (83 FR 19005, May 1, 2018), and as modified by prior inseason actions.

The RA determined that the best available information indicated that coho, Chinook salmon, and Pacific halibut abundance forecasts and expected fishery effort in 2018 supported the above inseason actions recommended by the states of Washington, Oregon, and California. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone consistent with these federal actions. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice of the described regulatory action was given, prior to the time the action was effective, by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF–FM and 2182 kHz.

Classification

NOAA's Assistant Administrator (AA) for NMFS finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B) because such notification would be impracticable. As previously noted, actual notice of the regulatory action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (83 FR 19005, May 1, 2018), the Pacific Coast Salmon Fishery Management Plan (FMP), and regulations implementing the FMP under 50 CFR 660.409 and 660.411. Prior notice and opportunity for public comment was impracticable because NMFS and the state agencies had insufficient time to provide for prior notice and the opportunity for public comment between the time coho, Chinook salmon, and Pacific halibut catch and effort projections and abundance forecasts were developed and fisheries impacts were calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best available scientific information, ensuring that conservation objectives and limits for impacts to salmon species listed under the Endangered Species Act are not exceeded. The AA also finds good cause to waive the 30-day delay in effectiveness required under 5 U.S.C. 553(d)(3), as a delay in effectiveness of this action would allow fishing at levels inconsistent with the goals of the FMP and the current management measures.

This action is authorized by 50 CFR 660.409 and 660.411 and is exempt from review under Executive Order 12866.

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

Dated: December 4, 2018.

Alan D. Risenhoover,

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

[FR Doc. 2018–26720 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 237
Tuesday, December 11, 2018

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–1008; Product Identifier 2018–NM–126–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. This proposed AD was prompted by reports indicating there is a possibility of excessive error in the signal generated by the angle of attack (AOA) transducer. This proposed AD would require replacing certain AOA transducers. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 25, 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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com*. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1008; 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 NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: John DeLuca, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7369; fax 516–794–5531; email *9-avs-nyaco-cos@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–2018–1008; Product Identifier 2018–NM–126–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM 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 NPRM.

Discussion

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2018–17, dated June 29, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The MCAI states:

> Bombardier has received reports from the manufacturer of its Angle of Attack (AOA) transducers indicating that there is a possibility of excessive error in the signal generated by the AOA Transducer. It is possible that this error may not be detected by the stall protection computer, which could lead to late stall protection system activation and potentially result in the loss of control of the aeroplane. The error could be a result of incorrect assembly or/and internal wear in the AOA Transducer.
>
> This [Canadian] AD mandates the modification or replacement of the AOA transducers in order to prevent late activation of the stick pusher in the stall protection system.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1008.

Related Service Information Under 1 CFR Part 51

Bombardier has issued Service Bulletin 601R–27–165, dated December 20, 2016. This service information describes procedures for replacing certain AOA transducers with new or modified AOA transducers. 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

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 the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. 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

on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in the service information described previously.

Differences Between This Proposed AD and the MCAI

The applicability of the MCAI is limited to Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes having serial number 7003 through 7067 inclusive and 7069 through 7891 inclusive, and equipped with AOA transducers having part number (P/N) 45–150–340, C16258AA, or C16258AB. However, the applicability of this proposed AD specifies Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes having serial number 7003 through 7067 inclusive and 7069 through 7891 inclusive. Airplanes having serial number 7003 through 7067 inclusive and 7069 through 7891 inclusive that are not equipped with the affected parts must comply with the parts installation prohibition specified in paragraph (h) of this proposed AD.

Costs of Compliance

We estimate that this proposed AD affects 525 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
5 work-hours × $85 per hour = $425	Up to $6,800	Up to $7,225	Up to $3,793,125

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

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 transport category airplanes and associated appliances to the Director of the System Oversight 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):

Bombardier, Inc.: Docket No. FAA–2018–1008; Product Identifier 2018–NM–126–AD.

(a) Comments Due Date

We must receive comments by January 25, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, having serial number 7003 through 7067 inclusive and 7069 through 7891 inclusive.

(d) Subject

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

(e) Reason

This AD was prompted by reports indicating there is a possibility of excessive error in the signal generated by the angle of attack (AOA) transducer. We are issuing this AD to address this potential error, which, if not detected by the stall protection computer, could lead to late activation of the stall protection system and possible loss of control of the airplane.

(f) Compliance

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

(g) Replacement of AOA Transducers

Within 9,000 flight hours or 46 months, whichever occurs first, after the effective date of this AD, replace the AOA transducers having part number (P/N) 45–150–340, C16258AA, or C16258AB, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R–27–165, dated December 20, 2016.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install any AOA transducer having P/N 45–150–340, C16258AA, or C16258AB, on any airplane.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2018–17, dated June 29, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1008.

(2) For more information about this AD, contact John DeLuca, Aerospace Engineer, Avionics and Electrical Systems Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7369; fax 516–794–5531; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* internet *http://www.bombardier.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on November 28, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–26627 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–1006; Product Identifier 2018–NM–142–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Gulfstream Aerospace LP Model Gulfstream G150 airplanes. This proposed AD was prompted by reports of corrosion in the solder joints of the upper and lower front relay box connectors to the printed circuit board. This proposed AD would require replacement of the existing relay boxes with modified boxes. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 25, 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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006; 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 NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

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–2018–1006; Product Identifier 2018–NM–142–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM 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 NPRM.

Discussion

The Civil Aviation Authority of Israel (CAAI), which is the aviation authority for Israel, has issued Israeli Airworthiness Directive ISR–I–24–2018–09–7, dated October 1, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Gulfstream Aerospace LP Model Gulfstream G150 airplanes. The MCAI states:

> The existing Upper and Lower Front Relay Box might be prone to corrosion in the relay box connector's solder joint to the printed circuit board. As a result various CAS [crew alerting system] messages such as slats unbalance and auto slats fail, Mach trim fail, etc. . . . might be reported [and could interfere with continued safe operation of the airplane]. To prevent this condition replacement of existing relay boxes with modified boxes featuring an added acrylic conformal coating should be performed.
>
> Five occurrences on G150 model in last 3 years had been reported.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006.

Related Service Information Under 1 CFR Part 51

Gulfstream has issued Service Bulletin 150–24–193, dated March 30, 2018. This service information describes procedures for removing and replacing the upper and lower front relay boxes.

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

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 the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. 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 on other products of the same type design.

Proposed Requirements of This NPRM

This proposed AD would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 81 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
220 work-hours × $85 per hour = $18,700	$20,083	$38,783	$3,141,423

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our cost estimate.

Authority for This Rulemaking

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

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

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 transport category airplanes to the Director of the System Oversight 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 LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.): Docket No. FAA–2018–1006; Product Identifier 2018–NM–142–AD.

(a) Comments Due Date

We must receive comments by January 25, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace LP (Type Certificate previously held by Israel Aircraft Industries, Ltd.) Model Gulfstream G150 airplanes, certificated in any category, serial numbers 201 through 326 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical power.

(e) Reason

This AD was prompted by reports of corrosion in the solder joints of the upper and lower front relay box connectors to the printed circuit board. We are issuing this AD to address corrosion in the front relay box connector solder joints. If not addressed, this condition could cause false crew alerting system (CAS) messages, such as slats unbalance, auto slats fail, and Mach trim fail, which could interfere with continued safe operation of the airplane.

(f) Compliance

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

(g) Replacement

Within 36 months after the effective date of this AD, remove the upper front relay box, Israel Aerospace Industries (IAI) part number (P/N) 25G8130301–510/–512/–514/–516, and replace with IAI P/N 25G8130301–516, upgraded to MOD A, and remove the lower front relay box, IAI P/N 25G8130300–512/–516/–518/–520, and replace with an improved lower front relay box, IAI P/N 25G8130300–520, upgraded to MOD A, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 150–24–193, dated March 30, 2018.

(h) Parts Installation Prohibition

As of the applicable compliance time specified in paragraph (h)(1) or (h)(2) of this AD, do not install relay box IAI P/N 25G8130301–510/–512/–514/–516 or IAI P/N 25G8130300–512/–516/–518/–520 on any airplane, except relay box IAI P/N 25G8130301–516 or IAI P/N 25G8130300–520 that has been upgraded to MOD A as specified in paragraph (g) of this AD may be installed.

(1) For airplanes that have IAI P/N 25G8130301–510/–512/–514/–516 or IAI P/N 25G8130300–512/–516/–518/–520 installed as of the effective date of this AD: After modification of the airplane as required by this AD.

(2) For airplanes that do not have IAI P/N 25G8130301–510/–512/–514/–516 or IAI P/N 25G8130300–512/–516/–518/–520 installed as of the effective date of this AD: As of the effective date of this AD.

(i) No Parts Return or Reporting Requirement

(1) Although Gulfstream Service Bulletin 150–24–193, dated March 30, 2018, specifies returning parts to the manufacturer, this AD does not include that requirement.

(2) Although Gulfstream Service Bulletin 150–24–193, dated March 30, 2018, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the Civil Aviation Authority of Israel (CAAI); or the CAAI's authorized Designee. If approved by the CAAI Designee, the approval must include the Designee's authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Israeli Airworthiness Directive ISR–I–24–2018–09–7, dated October 1, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(3) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on November 29, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–26623 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–1007; Product Identifier 2018–NM–141–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Airbus SAS Model A318 and A319 series airplanes, Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This proposed AD was prompted by a report that taperloks used in a certain wing-to-fuselage junction were found to be non-compliant with the applicable specification, resulting in a loss of pre-tension in the fasteners. This proposed AD would require repetitive special detailed inspections of the center and outer wing box lower stiffeners and panels at a certain junction on the left- and right-hand sides for any cracking, and repair if necessary. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 25, 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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For the incorporation by reference (IBR) material described in the ''Related IBR material under 1 CFR part 51'' section in **SUPPLEMENTARY INFORMATION**, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 1000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *http://www.regulations.gov.*

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1007; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer,

International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

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–2018–1007; Product Identifier 2018–NM–141–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM based on 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 NPRM.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0218, dated October 11, 2018; corrected October 26, 2018 (''EASA AD 2018–0218'') (also referred to as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A318 and A319 series airplanes, Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

> Taperloks used in the wing-to-fuselage junction at Rib 1 were found to be non-compliant with the applicable specification, resulting in a loss of pre-tension in the fasteners.
>
> This condition, if not detected and corrected, could affect the structural integrity of the aeroplane. To address this potential unsafe condition, Airbus issued SB A320–57–1129 and SB A320–57–1130, later revised twice, providing instructions for repetitive internal inspections of the lower stiffeners and for repetitive external inspections of the lower panels of the center and outer wing box at the level of Rib 1 junction. Consequently, EASA issued AD 2007–0067, later revised [which corresponds to FAA AD 2008–02–15, Amendment 39–15345 (73 FR 4063, January 24, 2008) (''AD 2008–02–15'')], to require accomplishment of these inspections.
>
> Since EASA AD 2007–0067R1 was issued, new events and the results of studies identified an aging effect on these parts. Prompted by these findings, Airbus revised SB A320–57–1129 (now at Revision 05) and A320–57–1130 (now at Revision 04), expanding the applicability, modifying the area to be inspected and updating the inspection intervals.
>
> For the reasons stated above, this [EASA] AD retains the requirements of EASA AD 2007–0067R1, which is superseded, expands the Applicability, modifies the areas to be inspected and revises the inspection thresholds and intervals.
>
> This [EASA] AD is republished to correct typographical errors in paragraph (2) and in Tables 1 and 3.

Relationship Between Proposed AD and AD 2008–02–15

This NPRM would not supersede AD 2008–02–15. Rather, we have determined that a stand-alone AD would be more appropriate to address the changes in the MCAI. This NPRM would require repetitive special detailed inspections of the center and outer wing box lower stiffeners and panels at the level of rib 1 junction on the left- and right-hand sides for any cracking, and repair if necessary. Accomplishment of the proposed actions would then terminate all of the requirements of AD 2008–02–15.

Related IBR Material Under 1 CFR Part 51

EASA AD 2018–0218 describes procedures for repetitive special detailed inspections of the center and outer wing box lower stiffeners and panels at the level of rib 1 junction on the left- and right-hand sides for any cracking, and repair if necessary. EASA AD 2018–0218 also provides procedures for an optional modification, which would terminate the repetitive inspections. This material 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 and it is publicly available through the EASA website.

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 the State of Design Authority, we have been notified of the unsafe condition described in the MCAI referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA worked with Airbus and the EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. As a result, EASA AD 2018–0218 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with the provisions specified in EASA AD 2018–0218, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information specified in EASA AD 2018–0218 that is required for compliance with EASA AD 2018–0218 will be available at *http://www.regulations.gov* under Docket No. FAA–2018–1007 after the FAA final rule is published.

Explanation of ''RC'' (Required for Compliance)

EASA AD 2018–0218, dated October 11, 2018; corrected October 26, 2018; might refer to service information that contains procedures or tests that are identified as RC. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an alternative method of compliance (AMOC), provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition.

Costs of Compliance

We estimate that this proposed AD affects 516 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
51 work-hours × $85 per hour = $4,335	$0	$4,335	$2,236,860

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

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
244 work-hours × $85 per hour = $20,740	$5,120	$25,860

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 transport category airplanes to the Director of the System Oversight 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):

Airbus SAS: Docket No. FAA–2018–1007; Product Identifier 2018–NM–141–AD.

(a) Comments Due Date

We must receive comments by January 25, 2019.

(b) Affected ADs

This AD affects AD 2008–02–15, Amendment 39–15345 (73 FR 4063, January 24, 2008) (''AD 2008–02–15'').

(c) Applicability

This AD applies to Airbus SAS Model A318–111, –112, –121, and –122 airplanes, Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes, Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes, certificated in any category, as identified in the European Aviation Safety Agency (EASA) AD 2018–0218, dated October 11, 2018; corrected October 26, 2018 (''EASA AD 2018–0218'').

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Reason

This AD was prompted by a report that taperloks used in the wing-to-fuselage junction at rib 1 were found to be non-compliant with the applicable specification, resulting in a loss of pre-tension in the fasteners. We are issuing this AD to address the loss of pre-tension in the fasteners, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0218.

(h) Exceptions to EASA AD 2018–0218

(1) For purposes of determining compliance with the requirements of this AD: Where EASA AD 2018–0218 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2018–0218 does not apply.

(3) Where EASA AD 2018–0218 refers to instructions provided by Airbus, for this AD, the instructions must be approved using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Terminating Action for AD 2008–02–15

Accomplishing the actions required by this AD terminates all requirements of AD 2008–02–15.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions

from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD: Any RC procedures and tests identified in the service information referenced in EASA AD 2018–0218 must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For information about EASA AD 2018–0218, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 6017; email *ADs@easa.europa.eu;* Internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this EASA AD at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. EASA AD 2018–0218 may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1007.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

Issued in Des Moines, Washington, on November 29, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–26624 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0990; Airspace Docket No. 18–AGL–13]

RIN 2120–AA66

Proposed Amendment of VOR Federal Airways V–128 and V–144 in the Vicinity of Kankakee, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend VHF Omnidirectional Range (VOR) Federal airways V–128 and V–144 in the vicinity of Kankakee, IL. The modifications are necessary due to the planned decommissioning of the Kankakee, IL (IKK), VOR navigation aid (NAVAID), which provides navigation guidance for portions of the affected air traffic service (ATS) routes. The Kankakee VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 25, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2018–0990; Airspace Docket No. 18–AGL–13 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

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

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

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2018–0990; Airspace Docket No. 18–AGL–13) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2018–0990; Airspace Docket No. 18–AGL–13.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking

documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

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

Background

The FAA is planning decommissioning activities for the Kankakee, IL (IKK), VOR in 2019 as one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082. Although the VOR portion of the Kankakee, IL, VOR/Distance Measuring Equipment (DME) NAVAID is planned for decommissioning, the DME portion is being retained. The ATS routes impacted by the Kankakee VOR are VOR Federal airways V–128 and V–144.

With the planned decommissioning of the Kankakee VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to V–128 and V–144 would result in the airways starting at the next NAVAID beyond the Kankakee VOR to avoid establishing gaps in the route structures. To overcome the loss of the airway segments proposed to be removed, instrument flight rules (IFR) traffic could use adjacent VOR Federal airways V–9, V–24, and V–227 between the Janesville, WI, VOR/DME and the Brickyard, IN, VOR/Tactical Air Navigation (VORTAC) or VOR Federal airways V–38 and V–156 between the Bradford, IL, VORTAC and the Fort Wayne, IN, VORTAC to circumnavigate the affected area. Additionally, IFR traffic could file point to point through the affected area using fixes that will remain in place, or receive air traffic control (ATC) radar vectors through the area. Visual flight rules pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to modify VOR Federal airways V–128 and V–144. The planned decommissioning of the Kankakee, IL, VOR has made these actions necessary. The proposed VOR Federal airway changes are outlined below.

V–128: V–128 currently extends between the Janesville, WI, VOR/DME and the Casanova, VA, VORTAC. The FAA proposes to remove the airway segment between the Janesville, WI, VOR/DME and the Brickyard, IN, VORTAC. The unaffected portions of the existing airway would remain as charted.

V–144: V–144 currently extends between the Bradford, IL, VORTAC and the Linden, VA, VOR/DME. The FAA proposes to remove the airway segment between the Bradford, IL, VORTAC and the Fort Wayne, IN, VORTAC. The unaffected portions of the existing airway would remain as charted.

All radials in the route descriptions below are unchanged and stated in True degrees.

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airways listed in this document would be subsequently published in the Order.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–128 [Amended]

From Brickyard, IN; INT Brickyard 137° and Cincinnati, OH, 290° radials; Cincinnati; York, KY; Charleston, WV; to Casanova, VA.

* * * * *

V–144 [Amended]

From Fort Wayne, IN; Appleton, OH; Zanesville, OH; Morgantown, WV; Kessel, WV; to Linden, VA.

Issued in Washington, DC, on December 3, 2018.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–26677 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0850; Airspace Docket No. 18–AWP–17]

RIN 2120–AA66

Proposed Amendment of Multiple Air Traffic Service (ATS) Routes; Western United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend three domestic Very High Frequency Omnidirectional Range (VOR) Federal Airways (V–113, V–137, and V–485) in the western United States. The modifications are necessary due to the planned decommissioning of Priest, CA, VOR navigation aid (NAVAID), which provides navigation guidance for portions of the affected air traffic service (ATS) routes. The Priest, CA, VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 25, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1 (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2018–0850; Airspace Docket No. 18–AWP–17 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

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

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

FOR FURTHER INFORMATION CONTACT: Kenneth Ready, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the National Airspace System as necessary to preserve the safe and efficient flow of air traffic.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2018–0850; Airspace Docket No. 18–AWP–17) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2018–0850; Airspace Docket No. 18–AWP–17.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

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

Background

The FAA is planning decommissioning activities for the Priest, CA, VOR in 2019 as one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the final policy statement notice, ''Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network),'' published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082. The ATS routes impacted by the Priest

VOR are VOR Federal airways V–113, V–137, V–485.

With the planned decommissioning of the Priest VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to V–113, V–137, and V–485 would result in gaps in the route structures.

To overcome the gap in V–113, instrument flight rules (IFR) traffic could use adjacent VOR Federal airways V–248 and V–107 between the Paso Robles, CA, VORTAC and the Panoche, CA, VORTAC.

V–137 is proposed to terminate at the Avenal, CA, VOR/DME instead of the Salinas, CA, VORTAC (current route termination point). Alternate course to reach the Salinas, CA, VORTAC is to file V–248.

V- 485 is proposed to terminate at the Fellows, CA, VOR/DME instead of the San Jose, CA, VOR/DME (current route termination point). Alternate course to reach San Jose, CA, VOR/DME is to file V–25. Additionally, ATS route T–333 is proposed to be extended as part of another rulemaking action that will mitigate the loss of V–485.

Lastly, IFR traffic could file point to point through the affected area using fixes that will remain in place, or receive air traffic control (ATC) radar vectors through the area. Visual flight rules pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent VOR Federal airways or ATC services listed previously.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to modify Domestic VOR Federal Airways (V–113, V–137 and V–485). The proposed route changes are outlined below.

V–113: V–113 currently extends between the Morro Bay, CA, VORTAC to the Lewistown, MT, VOR/DME. The FAA plans to delete the segment between the Paso Robles, CA, VORTAC and the Panoche, CA, VORTAC causing a gap in the route. The new route will stop at the Paso Robles, CA, VORTAC and resume at the Panoche, CA, VORTAC. The unaffected portion of the existing route will remain as charted.

V–137: V–137 currently extends between Mexicali, Mexico via the Imperial, CA, VORTAC to the Salinas, CA, VORTAC. The FAA plans to delete the segment between the Avenal, CA, VOR/DME and the Salinas, CA, VORTAC. The new route will end at the Avenal, CA, VOR/DME. The unaffected portion of the existing route will remain as charted.

V–485: V–485 currently extends between the Ventura, CA, VOR/DME to the San Jose, CA, VOR/DME. The FAA plans to delete the segment between the Fellows, CA, VOR/DME and the San Jose, CA, VOR/DME. The new route will end at the Fellows, CA, VOR/DME. The unaffected portion of the existing route will remain as charted.

Domestic VOR Federal Airways in paragraph 6010 of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Domestic VOR Federal Airways listed in this document will be subsequently published in the Order.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

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

Paragraph 6010(a) Domestic VOR Federal Airways

V–113 (Amended)

From Morro Bay, CA; to Paso Robles, CA. From Panoche, CA; to Linden, CA; INT Linden 046°(T) 029°(M) and Mustang, NV, 208°(T) 192°(M) radials; Mustang; 42 miles, 24 miles, 115 MSL, 95 MSL, Sod House, NV; 67 miles, 95 MSL, 85 MSL, Rome, OR; 61 miles, 85 MSL, Boise, ID; Salmon, ID; Coppertown, MT; Helena, MT; to Lewistown, MT.

* * * * *

V–137 (Amended)

From Mexicali, Mexico; via Imperial, CA; INT Imperial 350°(T) 336°(M) and Thermal, CA 144°(T) 131°(M) radials; Palm Springs, CA; Palmdale, CA; Gorman, CA; Avenal, CA. The airspace within Mexico is excluded.

* * * * *

V–485 (Amended)

From Ventura, CA; to Fellows, CA. The airspace within W–289 and R–2519 more than three (3) statute miles west of the airway centerline and the airspace within R–2519 below 5,000 feet MSL is excluded.

Issued in Washington, DC, on December 3, 2018.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2018–26679 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 681

RIN 3084–AB50

Identity Theft Rules

AGENCY: Federal Trade Commission.

ACTION: Request for public comment.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') requests public comment on its Identity Theft Rules. The Commission is soliciting comment as part of the FTC's systematic review of all current Commission regulations and guides.

DATES: Comments must be received on or before February 11, 2019.

ADDRESSES: Interested parties may file a comment online or on paper by:

• *Online:* Write ''Identity Theft Rules, 16 CFR part 681, Project No. 188402'' on

your comment and file your comment at *https://ftcpublic.commentworks.com/ftc/identitytheftrulesreview* by following the instructions on the web-based form.

• *Paper:* Write ''Identity Theft Rules, 16 CFR part 681, Project No. 188402'' on your comment and on the envelope and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

See the Instructions for Submitting Comments part of the **SUPPLEMENTARY INFORMATION** section below for additional information.

FOR FURTHER INFORMATION CONTACT: Stacy Procter, Western Region—Los Angeles Office, Bureau of Consumer Protection, Federal Trade Commission, 10990 Wilshire Blvd., Suite 400, Los Angeles, CA 90024, (310) 824–4300, or Amanda Koulousias, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, (202) 326–3334.

SUPPLEMENTARY INFORMATION:

I. Background

The Fair and Accurate Credit Transactions Act (''FACTA'') was enacted in December 2003.[1] Section 114 of FACTA amended section 615 of the Fair Credit Reporting Act (''FCRA'') and required the Commission and other federal agencies to establish and maintain guidelines for financial institutions and creditors to identify patterns, practices and activities that might indicate identity theft.[2] FACTA also required the Commission and other federal agencies to prescribe regulations requiring financial institutions and creditors to establish reasonable policies and procedures for implementing the established guidelines.[3] In addition, FACTA required the Commission and other federal agencies to prescribe regulations requiring debit and credit card issuers to validate notifications of changes of address under certain situations.[4]

In November 2007, the Commission and banking agencies published final rules and guidelines implementing the red flags provisions of section 615 of the FCRA.[5] These rules include the duties regarding the detection, prevention, and mitigation of identity theft (''Red Flags Rule'')[6] and the duties of card issuers regarding changes of address (''Card Issuers Rule'')[7] (collectively, the ''Identity Theft Rules'' or ''Rules''). In December 2010, the President signed the Red Flag Program Clarification Act (''Clarification Act''), which narrowed the scope of entities covered as a ''creditor'' under the Red Flags Rule.[8] The Clarification Act also empowers the Commission and other federal agencies to determine through rulemaking whether any other type of creditor should be subject to the Red Flags Rule based on whether such creditor offers or maintains accounts with a reasonably foreseeable risk of identity theft.[9]

The Red Flags Rule requires each ''financial institution'' and ''creditor'' subject to the Commission's enforcement authority to periodically determine whether it maintains ''covered accounts,'' and to develop and maintain a written Identity Theft Prevention Program (''Program'') to detect, prevent and mitigate identity theft in connection with the opening or existence of any ''covered account.''[10] Financial institutions or creditors that are required to implement a Program must administer the Program in accordance with the Red Flags Rule, consider the guidelines set forth in appendix A, and include in their Program those guidelines that are appropriate.[11] The Card Issuers Rule requires that debit or credit card issuers establish and implement reasonable policies and procedures to assess the validity of a change of address request if, within a short period of time after receiving the request, the card issuer receives a request for an additional or replacement card for the same account.[12] The Card Issuers Rule further prohibits a card issuer from issuing an additional or replacement card until it has (1) notified the cardholder of the request and provided a reasonable means for the cardholder to promptly report an incorrect address change, or (2) otherwise assessed the validity of the address change.[13] Card issuers within the FTC's jurisdiction include, for example, state credit unions, general retail merchandise stores, colleges and universities, and telecoms.

II. Regulatory Review of the Identity Theft Rules

The Commission periodically reviews all of its rules and guides. These reviews seek information about the costs and benefits of the agency's rules and guides, and their regulatory and economic impact. The information obtained assists the Commission in identifying those rules and guides that warrant modification or rescission. Therefore, the Commission solicits comments on, among other things, the economic impact and benefits of the Identity Theft Rules; possible conflict between the Identity Theft Rules and state, local, or other federal laws or regulations; and the effect on the Identity Theft Rules of any technological, economic, or other industry changes.

III. Issues for Comment

The Commission requests written comment on any or all of the following questions. These questions are designed to assist the public and should not be construed as a limitation on the issues about which public comments may be submitted. The Commission requests that responses to its questions be as specific as possible, including a reference to the question being answered, and refer to empirical data or other evidence upon which the comment is based whenever available and appropriate.

A. General Issues

1. Is there a continuing need for specific provisions of the Rules? Why or why not?

2. What benefits have the Rules provided to consumers? What evidence supports the asserted benefits?

3. What modifications, if any, should be made to the Rules to increase the benefits to consumers?

a. What evidence supports the proposed modifications?

[1] Public Law 108–159, 117 Stat. 1952 (codified as amended at 15 U.S.C. 1681–1681x).

[2] 15 U.S.C. 1681m(e)(1)(A), (e)(2). The other federal agencies include the Federal banking agencies, the National Credit Union Administration, the Commodity Futures Trading Commission (''CFTC'') and the Securities and Exchange Commission (''SEC''). The CFTC and SEC obtained regulatory authority in July 2010 pursuant to the Dodd Frank Wall Street Reform and Consumer Protection Act. Public Law 111–203, 124 Stat. 1376–2223.

[3] 15 U.S.C. 1681m(e)(1)(B).

[4] 15 U.S.C. 1681m(e)(1)(C).

[5] 72 FR 63718.

[6] 16 CFR 681.1.

[7] 16 CFR 681.2.

[8] Public Law 111–319, 124 Stat. 3457 (codified at 15 U.S.C. 1681m(e)(4)). The Clarification Act retains the definition of ''creditor'' from section 702 of the Equal Credit Opportunity Act (''ECOA''), 15 U.S.C. 1691a, but generally limits application of the Red Flags Rule to ECOA creditors that engage in certain conduct regularly and in the ordinary course of business.

[9] 15 U.S.C. 1681m(e)(4)(C).

[10] 16 CFR 681.1(c)–(d).

[11] 16 CFR 681.1(e)–(f).

[12] 16 CFR 681.2(c).

[13] Id.

b. How would these modifications affect the costs the Rules impose on businesses, including small businesses?

4. What significant costs, if any, have the Rules imposed on consumers? What evidence supports the asserted costs?

5. What modifications, if any, should be made to the Rules to reduce any costs imposed on consumers?

a. What evidence supports the proposed modifications?

b. How would these modifications affect the benefits provided by the Rules?

6. What benefits, if any, have the Rules provided to businesses, including small businesses? What evidence supports the asserted benefits?

7. What modifications, if any, should be made to the Rules to increase their benefits to businesses, including small businesses?

a. What evidence supports the proposed modifications?

b. How would these modifications affect the costs the Rules impose on businesses, including small businesses?

c. How would these modifications affect the benefits to consumers?

8. What significant costs, if any, including costs of compliance, have the Rules imposed on businesses, including small businesses? What evidence supports the asserted costs?

9. What modifications, if any, should be made to the Rules to reduce the costs imposed on businesses, including small businesses?

a. What evidence supports the proposed modifications?

b. How would these modifications affect the benefits provided by the Rules?

10. What evidence is available concerning the degree of industry compliance with the Rules?

11. What modifications, if any, should be made to the Rules to account for changes in relevant technology or economic conditions? What evidence supports the proposed modifications?

12. Do the Rules overlap or conflict with other federal, state, or local laws or regulations? If so, how?

a. What evidence supports the asserted conflicts?

b. With reference to the asserted conflicts, should the Rules be modified? If so, why, and how? If not, why not?

B. Specific Issues

1. Do the guidelines in appendix A of the Red Flags Rule need updating? If so, what updates should be made?

a. What evidence supports the proposed modification?

b. [Reserved]

2. The Red Flags Rule covers creditors that regularly and in the ordinary course of business: (1) Obtain or use consumer reports in connection with a credit transaction; (2) furnish information to consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, based on an obligation of the person to repay the funds or repayable from specific property pledged by or on behalf of the person, unless the expenses for which the funds are advanced are incidental to a service the creditor provides to that person. Is there any other type of creditor that is not subject to the Red Flags Rule that offers or maintains accounts that are subject to a reasonably foreseeable risk of identity theft?

a. If so, what type of creditor and what evidence supports that conclusion?

b. [Reserved]

IV. Instructions for Submitting Comments

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 11, 2019. Write ''Identity Theft Rules, 16 CFR part 681, Project No. 188402'' on the comment. Your comment, including your name and your state, will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at *https://www.ftc.gov/policy/public-comments.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission website. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as a Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or payment card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information.

In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comments to be withheld from the public record. Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/identitytheftrulesreview* by following the instructions on the web-based form. If this document appears at *https://www.regulations.gov,* you also may file a comment through that website.

If you file your comment on paper, write ''Identity Theft Rules, 16 CFR part 681, Project No. 188402'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

Visit the Commission website at *https://www.ftc.gov* to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 11, 2019. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2018–26609 Filed 12–10–18; 8:45 am]

BILLING CODE 6750–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2018–0384; FRL–9987–72–Region 5]

Air Plan Approval; Ohio; Revisions to Particulate Matter Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve assorted revisions to Ohio's particulate matter rules that the state requested EPA approve into the Ohio State Implementation Plan (SIP) under the Clean Air Act. One set of revisions address sources subject to a requirement for continuous opacity monitoring for which such monitoring is unreliable. The revisions add two alternatives; one alternative requires the source to conduct continuous emission monitoring, and the other alternative subjects the source to an alternative monitoring plan assessing compliance with limits specified for alternative parameters. Other revisions in the rule remove provisions for facilities that have shut down and make nonsubstantive revisions to the language of the rules.

DATES: Comments must be received on or before January 10, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2018–0384 at *http://www.regulations.gov,* or via email to *aburano.douglas@epa.gov*. For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, 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. 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: John Summerhays, Environmental Scientist, Attainment Planning and Maintenance, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6067, *summerhays.john@epa.gov*.

SUPPLEMENTARY INFORMATION: This supplementary information section is arranged as follows:

I. History of Submittal

The Ohio Environmental Protection Agency (Ohio [1]) is subject to requirements to review each of its regulations every five years, to assess whether any updates to the regulations are warranted and for other purposes. Accordingly, Ohio reviewed its regulations in Ohio Administrative Code (OAC) Chapter 3745–17, entitled ''Particulate Matter Standards,'' and adopted various revisions amending and updating these rules. Ohio then requested that EPA approve these revisions into the SIP, with exceptions discussed below, in a submittal dated June 1, 2018, along with an amended request submitted August 9, 2018.

As a result of its review, Ohio concluded that rule revisions were needed to address facilities subject to requirements for continuous opacity monitoring for which such monitoring does not provide reliable determinations of opacity. This concern especially applies to power plants that have installed wet flue gas desulfurization equipment. While power plants are generally required under OAC 3745–17–03(C) to implement continuous opacity monitoring, in accordance with requirements in Title 40 Code of Federal Regulations part 51, appendix P (40 CFR part 51, appendix P), plants with wet flue gas desulfurization equipment in some cases have water vapor in the flue gas that can render continuous opacity measurements unreliable.

To address this concern, Ohio revised its rules to offer two alternatives for plants subject to requirements for continuous opacity monitoring for which such monitoring is unreliable. The first alternative is to conduct continuous emissions monitoring. The second alternative is to conduct monitoring of operational parameters that are identified as suitable for determining compliance with particulate emission limitations. Further description of these alternatives and the requirements that Ohio adopted in association with these requirements are described in the following section.

Ohio's June 1, 2018 submittal only requested approval of the second of these alternatives. However, on August 9, 2018, Ohio revised its request to ask that EPA approve both alternatives. Accordingly, this rulemaking addresses both alternatives.

A second set of revisions Ohio made to its rules was to clarify that appliances for residential wood combustion are not subject to the limitations in Ohio's particulate matter regulations. A third set of revisions removed provisions that are no longer necessary because the affected facility has shut down. A final set of revisions modified the wording of selected text to reflect new semantic preferences.

Previous revisions to the rules in OAC Chapter 3745–17 provided a category of power plants operating continuous opacity monitoring systems the option to demonstrate compliance with an alternate set of opacity limits. Ohio requested approval of those revisions on June 4, 2003, but EPA proposed to disapprove those revisions on June 27, 2005, at 70 FR 36901. Subsequently, on September 5, 2014, Ohio withdrew its submittal of these revisions. While these provisions remain part of OAC 3745–17–03, Ohio's June 1, 2018 submittal clarifies that the state is not requesting EPA action on these provisions.

II. Review of Alternatives to Continuous Opacity Monitoring

As noted above, the existing Ohio SIP includes provisions that, in accordance with 40 CFR part 51, appendix P, facilities meeting the criteria of appendix P, notably including most power plants, must operate continuous opacity monitoring systems. However, the installation of wet flue gas desulfurization control equipment on power plants commonly increases the quantity of water vapor within the stack, which in some cases has rendered the continuous opacity monitoring unreliable. This problem has led to consideration of alternative approaches for providing continuous monitoring of whether particulate matter emission controls are operating properly.

[1] To avoid confusion, this notice uses the term ''Ohio'' as shorthand for the Ohio Environmental Protection Agency and the term ''EPA'' as shorthand for the United States Environmental Protection Agency.

Limits on opacity complement limits on particulate mass emissions in assuring that the particulate matter emission controls that are part of the plan for attaining particulate matter air quality standards are operating properly. Stack tests provide a more direct measure of the quantitative efficiency of the control of particulate matter mass, at least with respect to filterable particulate matter (since most limits and therefore most stack tests do not measure condensable particulate matter). On the other hand, opacity observations generally provide a more convenient and less costly measure of particulate matter control, which when done by human observers (in accordance with Method 9) are designed to address condensable as well as filterable particulate matter. Opacity monitoring can also readily be conducted continuously using in-stack monitoring equipment. Therefore, EPA promulgated appendix P to provide for continuous opacity monitoring, most notably for power plants, to provide more continuous evidence as to whether the affected sources are controlling their particulate matter emissions appropriately. The primary criterion of this rulemaking, then, is whether any alternative monitoring that becomes authorized under this rule for any facility provides an appropriate continuous assessment of the effectiveness of particulate matter emission control that is comparable to the continuous assessment that EPA sought to achieve by promulgating appendix P.

The first alternative that Ohio incorporated into OAC 3745–17–03 was continuous monitoring of the mass of particulate emissions. As specified in OAC 3745–17–03(D), such monitoring is to be conducted in accordance with EPA's Performance Specification 11, as given in 40 CFR part 60, appendix B. Facilities seeking to use this alternative in lieu of continuous opacity monitoring must request permission from Ohio and from EPA. Facilities authorized to use this alternative must comply with a limit of 0.03 pounds of particulate matter per million British Thermal Units (lbs/MMBTU) on a 24-hour average basis (based on an average of all hourly average emission rates over a calendar day period) as well as any other limit in OAC Chapter 3745–17 to which the facility is subject. OAC 3745–17–03(D) authorizes changes in routine monitoring of pertinent sources but does not relax any limits to which an affected source is subject. Notably, opacity in excess of the 20 percent limit in the SIP that is observed through Method 9 remains a violation of the SIP, in a manner that is unaffected by OAC 3745–17–03(D) or its prospective usage in specific cases. Thus, for example, cases involving substantial emissions of condensable particulate matter sufficient to cause violation of the 20 percent opacity limit would still be grounds for enforcement action, independent of whether any filterable particulate matter emission measurements have been made.

Continuous emissions monitoring by its nature provides continuous information on how well the source is controlling particulate matter emissions as continuous opacity monitoring. Given the mass and opacity limits that apply, EPA believes that the two approaches provide comparable measures of how well the source is controlling particulate matter emissions. OAC 3745–17–03(D) provides that Ohio and EPA will review the situation for each facility on a case-by-case basis to assure that use of continuous emission monitoring in lieu of continuous opacity monitoring is warranted. For these reasons, EPA believes that OAC 3745–17–03(D) provides a suitable alternative means for facilities in appropriate cases to assess the adequacy of particulate matter emission control in lieu of continuous opacity monitoring.

The second alternative to continuous opacity monitoring provided in OAC 3745–17–03 is the continuous monitoring of operational parameters. For example, in selected cases, EPA accepts baghouse leak detection systems as a suitable alternative to continuous opacity monitoring. Under OAC 3745–17–03(E), facilities seeking to conduct parameter monitoring in lieu of continuous opacity monitoring must submit a request that includes a proposed monitoring plan. This plan must specify the parameters to be monitored, the parameters must be indicative of whether the facility is complying with the applicable mass and opacity limitations to which the facility is subject, and the plan must specify the acceptable range of values of the parameters that are to be required to be met. OAC 3745–17–03(E) states that parameter values outside the range specified as indicative of compliance shall constitute a federally enforceable violation of facility control requirements. Upon approval by Ohio and EPA, the facility is then subject to this monitoring plan in lieu of being required to conduct continuous opacity monitoring.

As with OAC 3745–17–03(D), OAC 3745–17–03(E) does not relax any limits to which the source is subject. For example, observations using Method 9 indicating a violation of the 20 percent opacity limit in the SIP would remain grounds by which a source with excessive particulate matter emissions (whether filterable particulate matter or condensable particulate matter or both) could be identified and subject to enforcement action as violating opacity limits. In a limited number of cases, the monitoring of the operations of a facility and its control equipment (*e.g.,* the monitoring of whether any bags in a baghouse are leaking) can provide a comparable measure of whether particulate matter emissions are being appropriately controlled as a more direct measurement of opacity or particulate matter mass. OAC 3745–17–03(E) authorizes the use of such parameter monitoring in lieu of continuous opacity monitoring, in the subset of these cases ''where the use of a [continuous opacity monitoring system] would not provide accurate determinations of opacity.'' Under these circumstances, EPA believes that OAC 3745–17–03(E) provides a suitably constrained opportunity for facilities to conduct parameter monitoring in lieu of opacity monitoring. OAC 3745–17–03(E) requires the approval of both Ohio and EPA, and the rule stipulates that the parameter monitoring is to be a reliable indicator of whether the facility is complying with applicable limits. That is, EPA views this alternative as being available only in facility-specific circumstances where continuous opacity monitoring is unreliable and where parameter monitoring provides reliable, continuous assessment of control effectiveness comparable to the level of compliance monitoring that EPA intended by promulgating appendix P. For this subset of facilities, EPA believes that parameter monitoring can provide a suitable alternative approach to continuous compliance monitoring.

III. Review of Other Rule Revisions

As summarized above, Ohio's revisions to OAC Chapter 3745–17, besides the addition of alternatives to continuous opacity monitoring discussed in the previous section, include clarification that OAC Chapter 3745–17 rules do not regulate residential wood combustion, removal of provisions that pertain to facilities that have shut down, and modification of wording for phrases that Ohio wishes to rephrase.

Chapter 3745–17 includes 11 rules, extending from 3745–17–01 to 3745–17–14 but not including adopted but now rescinded rules numbered 3745–17–02, 3745–17–05, or 3745–17–06.

Ohio revised all 11 of these remaining rules.

Rule 3745–17–02, entitled ''Air Quality Standards,'' was previously moved to OAC Chapter 3745–25 for consolidation with air quality standards for other pollutants. EPA approved the moved rule, in OAC 3745–25–02, in an action published on October 26, 2010, at 75 FR 65572, but EPA did not approve the rescission of OAC 3745–17–02. Therefore, EPA is proposing to approve the rescission of OAC 3745–17–02 as part of this action. OAC 3745–17–05 and 3745–17–06 have already been rescinded from the SIP.

The following discussion reviews each rule's revisions individually.

—3745–17–01, ''Definitions''—The primary revisions to OAC 3745–17–01 are to add definitions of various terms pertaining to residential wood combustion, including central heater, chip wood fuel, fireplace, pellet fuel, pellet stove, residential force air furnace, residential hydronic heater, residential masonry heater, residential wood burning appliance, and wood heater. These definitions are sensible definitions that clearly establish appropriate categories of sources for use in other regulations. The appropriateness of the regulatory provisions in other rules based on these definitions is reviewed as part of the review of the other rules. This rule also includes reasonable additions to the reference material that is used in evaluating compliance with the provisions of OAC Chapter 3745–17.

—3745–17–03—''Measurement Methods and Procedures''—The primary revisions in this rule are the addition of the two alternatives to compliance with requirements for continuous opacity monitoring. These revisions were reviewed in the prior section of this preamble.

While Ohio requested approval of most of OAC 3745–17–03, Ohio expressly excluded two elements of OAC 3745–17–03 from this request. One of these elements, in OAC 3745–17–03(B)(1)(b), offers an alternate opacity limit (in brief, authorizing 1.1 percent of nonexempt 6-minute opacity values to exceed 20 percent opacity) for power plants operating continuous opacity monitoring systems. The second, associated element is the phrase in OAC 3745–17–03(B)(1)(a) stating ''Except as provided in paragraph (B)(1)(b) of this rule''. These are provisions that Ohio submitted on June 4, 2003, that EPA proposed to disapprove on June 27, 2005, and that Ohio withdrew from consideration on September 5, 2014. Accordingly, EPA is proposing to act on most of OAC 3745–17–03, notably including paragraphs 3745–17–03(D) and (E), but EPA is proposing not to act on subparagraph 3745–17–03(B)(1)(b) and the specified phrase in 3745–17–03(B)(1)(a).

Revised OAC 3745–17–03 modifies the reference method for measuring opacity, which previously only identified Method 9 (in 40 CFR 60 appendix A), to include ''USEPA method 9 or continuous opacity monitoring as specified in paragraph (C) of this rule.'' These two methods make different measurements, notably insofar as Method 9 involves human observations which consider the effect of condensable particulate matter (*i.e.,* material that is in gaseous form in the stack but condenses into solid form after leaving the stack), whereas in-stack continuous opacity monitoring does not. The in-stack continuous opacity monitoring will understate opacity (and understate this indicator or particulate emissions) to the extent that it excludes condensable particulate matter, but EPA generally considers suitable continuous opacity monitoring indicating noncompliance to be actionable basis for concluding that particulate matter emission control is inadequate. EPA understands the revised rule to provide that measurements by either method that indicate a violation of opacity limits shall constitute evidence of noncompliance, regardless of whether data based on the other method are available or whether data based on the other method indicate compliance.

Revised OAC 3745–17–03 also contains a small number of editorial revisions, for example converting singular/plural constructions to the plural (*e.g.,* converting ''charge(s)'' to ''charges'') and removing selected unnecessary text (simplifying ''in accordance with the requirements of 'USEPA Performance Specification 1' '' to ''in accordance with 'USEPA Performance Specification 1' ''). These editorial revisions yield an equally acceptable regulation.

—3745–17–04—''Compliance Time Schedules''—The primary revisions in this rule are the removal of provisions that apply to facilities that have shut down. Ohio also adopted numerous editorial simplifications in this rule, for example to remove the phrase ''the requirements of'' where this phrase is unnecessary. These revisions do not alter the substantive requirements of this rule, and so the revised rule is approvable.

—3745–17–07—''Control of Visible Particulate Emissions from Stationary Sources''—Ohio added residential wood burning appliances and pellet stoves as explicitly exempted from the opacity limits in this rule. This rule had already exempted sources that are not subject to mass emission limits in specified other rules. Residential wood burning appliances and pellet stoves are not subject to the mass emission limits in the specified other rules, and so these sources were already exempt from the opacity limits of OAC 3745–17–07. Thus, the addition of an explicit exemption for these sources does not relax the requirements of the SIP, and instead merely clarifies that these sources are exempt from the opacity limits of OAC 3745–17–07.

Ohio also removed source-specific opacity limits for sources that have shut down, and Ohio made editorial revisions similar to those discussed above. These revisions are approvable.

—3745–17–08—''Restriction of Emission of Fugitive Dust''—The primary revisions in this rule are the removal of provisions that applied only to sources that have now shut down and editorial revisions similar to those discussed above. Also, for sources that are to apply for a permit to address nuisances, Ohio revised OAC 3745–17–08 to reflect revised permitting procedures implemented in other Ohio rules since OAC Chapter 3745–17 was last revised. Finally, Ohio added maps to illustrate the areas that are subject to long-standing requirements for reasonably available control measures. These revisions result in an equally protective set of rules and are approvable.

—3745–17–09—''Restrictions on Particulate Emissions and Odors from Incinerators''—Ohio reformatted the text of this regulation but made no substantive changes. These revisions are approvable.

—3745–17–10—''Restrictions on Particulate Emissions from Fuel-burning Equipment''—Ohio removed provisions that are moot due to shutdown of an affected facility, and Ohio made editorial revisions similar to those discussed above. These revisions are approvable.

—3745–17–11—''Restrictions on Particulate Emissions from Industrial Processes''—Ohio added a handful of clarifications to this rule. OAC 3745–17–11 is Ohio's process weight rule, *i.e.,* a rule that imposes limits that are a function of the weight of materials that a facility processes. The rule has special provisions for surface coating operations; Ohio amended the text to

clarify that only surface coaters that are exempt based on usage of less than five gallons of coatings per day must keep records on coatings usage; Ohio also amended this provision to require that such sources also keep records of coating method. Ohio codified long-standing policy that the process weight used in determining the limit under this rule does not include ''liquid and gaseous fuels when they are used solely as fuels and combustion air.'' Ohio further made assorted editorial and correcting amendments, such as correcting a source's address. These revisions result in an equally protective set of rules and are approvable.

—3745–17–12—''Additional Restrictions on Particulate Emissions from Specific Air Contaminant Sources in Cuyahoga County''—Most of the revisions to this rule are to remove provisions that are moot due to shutdown of the affected source. Ohio also updated the names of companies in applicable cases. These revisions have no substantive effect on the requirements of the rule and are approvable.

—3745–17–13—''Additional Restrictions on Particulate Emissions from Specific Air Contaminant Sources in Jefferson County''—As with OAC 3745–17–12, the revisions to OAC 3745–17–13 remove the provisions that apply to sources that no longer operate and update the names of affected companies where appropriate. These revisions have no substantive effect on the requirements of the rule and are approvable.

—3745–17–14—''Contingency Plan Requirements for Cuyahoga and Jefferson Counties''—The primary revisions to this rule are to remove companies that are no longer operating. Ohio also made editorial revisions similar to those discussed above. These revisions are approvable.

IV. What action is EPA taking?

EPA is proposing to approve the rules in OAC 3745–17 that Ohio requested be approved. A full listing of the rules that EPA is proposing to approve is provided in Table 1. EPA is proposing to approve the entirety of all of these rules except for OAC 3745–17–03, for which Ohio's request excluded specified sections. In addition, EPA is proposing to remove OAC 3745–17–02, which Ohio has rescinded and the substance of which has been recodified (and approved into the SIP) within OAC 3745–25–02.

TABLE 1—OAC 3745–17 ''PARTICULATE MATTER STANDARDS,'' EFFECTIVE JANUARY 20, 2018

Rule No.	Rule title	Portion proposed for approval
3745–17–01	Definitions	Entirety.
3745–17–03	Measurement Methods and Procedures	All except paragraph (B)(1)(b) and the reference to that paragraph in paragraph (B)(1)(a).
3745–17–04	Compliance Time Schedules	Entirety.
3745–17–07	Control of Visible Particulate Emissions from Stationary Sources	Entirety.
3745–17–08	Restriction of Emission of Fugitive Dust	Entirety.
3745–17–09	Restrictions on Particulate Emissions and Odors from Incinerators	Entirety.
3745–17–10	Restrictions on Particulate Emissions from Fuel-burning Equipment	Entirety.
3745–17–11	Restrictions on Particulate Emissions from Industrial Processes	Entirety.
3745–17–12	Additional Restrictions on Particulate Emissions from Specific Air Contaminant Sources in Cuyahoga County.	Entirety.
3745–17–13	Additional Restrictions on Particulate Emissions from Specific Air Contaminant Sources in Jefferson County.	Entirety.
3745–17–14	Contingency Plan Requirements for Cuyahoga and Jefferson Counties	Entirety.

V. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the Ohio particulate matter rules discussed in section IV. ''What Action is EPA Taking?'' of this preamble. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the ''For Further Information Contact'' section of this preamble for more information).

VI. 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 Clean Air 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).

List of Subjects in 40 CFR Part 52

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

Dated: November 27, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2018–26780 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 83, No. 237
Tuesday, December 11, 2018

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.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Tennessee Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice 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 Tennessee Advisory Committee will hold a public hearing to hear testimony on the civil rights issues related to legal financial obligations in Tennessee.

DATES: Tuesday, January 8, 2019 from 09:45 a.m.–4:30 p.m.

ADDRESSES: Nashville Public Library, 615 Church Street, Nashville, Tennessee 37219

FOR FURTHER INFORMATION CONTACT: Jeff Hinton, GFO, at *jhinton@usccr.gov.*

SUPPLEMENTARY INFORMATION: Members of the public are invited to come in and listen to the discussion. Written comments will be accepted until February 8, 2019 and may be mailed to the Regional Program Unit Office, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or may be emailed to Jeff Hinton at *jhinton@usccr.gov.* Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Tennessee 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 Southern Regional Office at the above email or street address.

Agenda

- ☐ Opening Remarks and Introductions (9:45 a.m.–9:55 a.m.)
- ☐ Panel 1: (10:00 a.m.–10:55 a.m.)
- ☐ Panel 2: (11:00 a.m.–11:55 a.m.)
- ☐ Open Forum/Personal Testimony: (12:00 p.m.–12:30 p.m.)
- ☐ Break (12:30 p.m.–2:30 p.m.)
- ☐ Panel 3: (1:30 p.m.–2:255 p.m.)
- ☐ Panel 4: (2:30 p.m.–3:55 p.m.)
- ☐ Open Forum (4:00–4:30 p.m.)
- ☐ Adjournment

Dated: December 5, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–26743 Filed 12–10–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority

First Responder Network Authority Combined Committee and Board Meeting

AGENCY: First Responder Network Authority (FirstNet), National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of public meeting of the First Responder Network Authority Board.

SUMMARY: The Board of the First Responder Network Authority (Board) will convene an open public meeting of the Board and the Board Committees on December 13, 2018.

DATES: A joint meeting of the four FirstNet Board Committees and the FirstNet Board will be held on December 13, 2018, between 11:00 a.m. and 2:30 p.m. (ET). The meeting of the FirstNet Board and the Governance and Personnel, Technology, Consultation and Outreach, and Finance Committees will be open to the public from 11:00 a.m. to 2:30 p.m. (ET).

ADDRESSES: The meeting on December 13, 2018 will be held at the Hyatt Regency Tysons Corner Center, 7901 Tysons One Place, McLean, VA 22102. Members of the public may listen to the meeting by dialing toll free 1–888–469–2980 and entering participant code 4810197#.

FOR FURTHER INFORMATION CONTACT: Karen Miller-Kuwana, Board Secretary, FirstNet, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192; telephone: (571) 665–6177; email: *Karen.Miller-Kuwana@firstnet.gov.* Please direct media inquiries to Ryan Oremland at (571) 665–6186.

SUPPLEMENTARY INFORMATION: This notice informs the public that the FirstNet Board and the Board Committees will convene an open public meeting on December 13, 2018.

Background: The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Title VI, 126 Stat. 256 (codified at 47 U.S.C. 1401 *et seq.*)) (Act) established FirstNet as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs FirstNet to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Board is responsible for making strategic decisions regarding FirstNet's operations. The FirstNet Board held its first public meeting on September 25, 2012.

Matters to be Considered: FirstNet will post a detailed agenda for the Combined Board Committees and Board Meeting on its website, *http://www.firstnet.gov,* prior to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the Committees and the Board may involve commercial or financial information that is privileged or confidential or other legal matters affecting FirstNet. As such, the Committee Chairs and Board Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

Times and Dates of Meeting: A combined meeting of the FirstNet Board and FirstNet Board Committees will be held on December 13, 2018 between 11:00 a.m. and 2:30 p.m. (ET). The meeting of the FirstNet Board and the Governance and Personnel, Technology, Consultation and Outreach, and Finance Committees will be open to the public from 11:00 a.m. to 2:30 p.m. (ET). The times listed above are subject to change. Please refer to FirstNet's website at *www.firstnet.gov* for the most up-to-date information.

Place: The meetings on December 13, 2018 will be held at the Hyatt Regency Tysons Corner Center, 7901 Tysons One Place, McLean, VA 22102. Members of the public may listen to the meeting by

dialing toll free 1–888–469–2980 and entering participant code 4810197#.

Other Information: These meetings are open to the public and press on a first-come, first-served basis. Space is limited. To ensure an accurate headcount, all expected attendees are asked to provide notice of intent to attend by sending an email to *BoardRSVP@firstnet.gov.* If the number of RSVPs indicates that expected attendance has reached its capacity, FirstNet will respond to all subsequent notices indicating that capacity has been reached and that in-person viewing may no longer be available but that the meeting may still be viewed by webcast as detailed below. For access to the meetings, valid government issued photo identification may be requested for security reasons.

The Combined Committee and Board Meetings are accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Ms. Miller-Kuwana by telephone (571) 665–6177 or email at *Karen.Miller-Kuwana@firstnet.gov* at least five (5) business days before the applicable meeting.

The meeting will also be webcast. Please refer to FirstNet's website at *www.firstnet.gov* for webcast instructions and other information. Viewers experiencing any issues with the live webcast may email *support@sparkstreetdigital.com* or call 202–684–3361 x3 for support. A variety of automated troubleshooting tests are also available via the ''Troubleshooting Tips'' button on the webcast player. The meetings will also be available to interested parties by phone. To be connected to the meetings in listen-only mode by telephone, please dial toll free 1–888–469–2980 and enter participant code 4810197#. If you experience technical difficulty, please contact the Conferencing Center customer service at 1–866–900–1011.

Records: FirstNet maintains records of all Board proceedings. Minutes of the Board Meeting and the Committee meetings will be available at *www.firstnet.gov.*

Dated: December 3, 2018.

Karen Miller-Kuwana,

Board Secretary, First Responder Network Authority.

[FR Doc. 2018–26600 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–TL–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–218–2018]

Foreign-Trade Zone 24—Pittston, Pennsylvania; Application for Subzone; adidas America, Inc.; Wilkes-Barre, Pennsylvania

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Eastern Distribution Center, Inc., grantee of FTZ 24, requesting subzone status for the facility of adidas America, Inc., located in Wilkes-Barre, Pennsylvania. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on December 4, 2018.

The proposed subzone (89.39 acres) is located at 550 New Commerce Blvd., Wilkes-Barre. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 24.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 22, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to February 4, 2019.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: December 4, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–26769 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–50–2018]

Foreign-Trade Zone (FTZ) 41—Milwaukee, Wisconsin; Authorization of Production Activity; Generac Power Systems, Inc. (Outdoor Power Equipment, Pumps, and Lawn and Garden Equipment); Jefferson and Whitewater, Wisconsin

On August 6, 2018, Generac Power Systems, Inc. (Generac) submitted a notification of proposed production activity to the FTZ Board for its facilities within Subzone 41J, in Jefferson and Whitewater, Wisconsin.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 42108–42109, August 20, 2018). On December 4, 2018, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14, and further subject to a restriction requiring that foreign-status disposable textile bag liners and lithium-ion batteries be admitted to the subzone in privileged foreign status (19 CFR 146.41).

Dated: December 4, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–26768 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 181108999–8999–01]

RIN 0694–XC051

Impact of the Implementation of the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving ''Schedule 1'' Chemicals (Including Schedule 1 Chemicals Produced as Intermediates) During Calendar Year 2018

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact that implementation of the Chemical

Weapons Convention (CWC), through the Chemical Weapons Convention Implementation Act and the Chemical Weapons Convention Regulations (CWCR), has had on commercial activities involving ''Schedule 1'' chemicals during calendar year 2018. The purpose of this notice of inquiry is to collect information to assist BIS in its preparation of the annual certification to the Congress on whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms are harmed by such implementation. This certification is required under Condition 9 of Senate Resolution 75 (April 24, 1997), in which the Senate gave its advice and consent to the ratification of the CWC.

DATES: Comments must be received by January 10, 2019.

ADDRESSES: You may submit comments by any of the following methods (please refer to RIN 0694–XC051 in all comments and in the subject line of email comments):

- *Federal rulemaking portal* (*http://www.regulations.gov*)—you can find this notice by searching on its *regulations.gov* docket number, which is BIS–2018–0032;
- *Email: willard.fisher@bis.doc.gov*—include the phrase ''Schedule 1 Notice of Inquiry'' in the subject line;
- *Fax:* (202) 482–3355 (Attn: Willard Fisher);
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for ''Schedule 1'' chemicals, contact Douglas Brown, Treaty Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–2163. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction, commonly called the Chemical Weapons Convention (CWC or ''the Convention''), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 9, titled ''Protection of Advanced Biotechnology,'' calls for the President to certify to Congress on an annual basis that ''the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1.'' On July 8, 2004, President Bush, by Executive Order 13346, delegated his authority to make the annual certification to the Secretary of Commerce.

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization for the Prohibition of Chemical Weapons (OPCW). The CWC imposes certain obligations on countries that have ratified the Convention (*i.e.,* States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons, and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties in order to achieve the object and purpose of the Convention and the implementation of its provisions. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not engaged in activities prohibited under the CWC.

''Schedule 1'' chemicals consist of those toxic chemicals and precursors set forth in the CWC ''Annex on Chemicals'' and in ''Supplement No. 1 to part 712—SCHEDULE 1 CHEMICALS'' of the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710–722). The CWC identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC (Part VI of the ''Verification Annex'') restricts the production of ''Schedule 1'' chemicals for protective purposes to two facilities per State Party: A single small-scale facility (SSSF) and a facility for production in quantities not exceeding 10 kg per year. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103–21 defined the term ''protective purposes'' to mean ''used for determining the adequacy of defense equipment and measures.'' Consistent with this definition and as authorized by Presidential Decision Directive (PDD) 70 (December 17, 1999), which specifies agency and departmental responsibilities as part of the U.S. implementation of the CWC, the Department of Defense (DOD) was assigned the responsibility to operate these two facilities. Although this assignment of responsibility to DOD under PDD–70 effectively precluded commercial production of ''Schedule 1'' chemicals for protective purposes in the United States, it did not establish any limitations on ''Schedule 1'' chemical activities that are not prohibited by the CWC. However, DOD does maintain strict controls on ''Schedule 1'' chemicals produced at its facilities in order to ensure accountability for such chemicals, as well as their proper use, consistent with the object and purpose of the Convention.

The provisions of the CWC that affect commercial activities involving ''Schedule 1'' chemicals are implemented in the CWCR (see 15 CFR 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR 745), both of which are administered by the Bureau of Industry and Security (BIS). Pursuant to CWC requirements, the CWCR restrict commercial production of ''Schedule 1'' chemicals to research, medical, or pharmaceutical purposes. The CWCR prohibit commercial production of ''Schedule 1'' chemicals for ''protective purposes'' because such production is effectively precluded per PDD–70, as described above—see 15 CFR 712.2(a). The CWCR also contain other requirements and prohibitions that apply to ''Schedule 1'' chemicals and/or ''Schedule 1'' facilities. Specifically, the CWCR:

(1) Prohibit the import of ''Schedule 1'' chemicals from States not Party to the Convention (15 CFR 712.2(b));

(2) Require annual declarations by certain facilities engaged in the production of ''Schedule 1'' chemicals in excess of 100 grams aggregate per calendar year (*i.e.,* declared ''Schedule 1'' facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));

(3) Provide for government approval of ''declared Schedule 1'' facilities (15 CFR 712.5(f));

(4) Provide that ''declared Schedule 1'' facilities are subject to initial and routine inspection by the OPCW (15 CFR 712.5(e) and 716.1(b)(1));

(5) Require 200 days advance notification of establishment of new ''Schedule 1'' production facilities producing greater than 100 grams aggregate of ''Schedule 1'' chemicals per calendar year (15 CFR 712.4);

(6) Require advance notification and annual reporting of all imports and exports of ''Schedule 1'' chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and

(7) Prohibit the export of ''Schedule 1'' chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

For purposes of the CWCR (see 15 CFR 710.1), ''production of a Schedule 1 chemical'' means the formation of ''Schedule 1'' chemicals through chemical synthesis, as well as processing to extract and isolate ''Schedule 1'' chemicals produced by a biochemical or biologically mediated reaction. Such production is understood, for CWCR declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within a defined chemical manufacturing sequence, where such intermediates, by-products, or waste products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur.

Request for Comments

In order to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are significantly harmed by the limitations of the Convention on access to, and production of, ''Schedule 1'' chemicals as described in this notice, BIS is seeking public comments on any effects that implementation of the CWC, through the Chemical Weapons Convention Implementation Act and the CWCR, has had on commercial activities involving ''Schedule 1'' chemicals during calendar year 2018. To allow BIS to properly evaluate the significance of any harm to commercial activities involving ''Schedule 1'' chemicals, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice. The Department requires that all comments be submitted in written form. BIS will consider all comments received on or before January 10, 2019. All comments (including any personally identifying information or information for which a claim of confidentially is asserted either in those comments or their transmittal emails) will be made available for public inspection and copying. Parties who wish to comment anonymously may do so by submitting their comments via *Regulations.gov*, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself.

Dated: December 3, 2018.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2018–26734 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with October anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 30 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce has found that determinations concerning whether particular companies should be ''collapsed'' (*e.g.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*e.g.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (Q&V) Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[2] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single antidumping duty deposit rate. It is Commerce's policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[4] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to Commerce no later than 30 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

For exporters and producers who submit a separate-rate status application or certification and subsequently are selected as mandatory respondents, these exporters and producers will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews:

[2] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[3] Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (*e.g.,* an ongoing administrative review, new shipper review, *etc.*) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

[4] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than October 31, 2019.

	Period to be reviewed
Antidumping Duty Proceedings	
AUSTRALIA: Certain Hot-Rolled Steel Flat Products, A–602–809	10/1/17–9/30/18
BlueScope Steel, Ltd.	
BlueScope Steel Americas, Inc.	
Steelscape LLC.	
JAPAN: Certain Hot-Rolled Steel Flat Products, A–588–874	10/1/17–9/30/18
Hanwa Co., Ltd.	
Higuchi Manufacturing America, LLC.	
Higuchi Seisakusho Co., Ltd.	
Hitachi Metals, Ltd.	
Honda Trading Canada, Inc.	
JFE Shoji Trade America.	
JFE Shoji Trade Corporation.	
JFE Steel Corporation.	
Kanematsu Corporation	
Kobe Steel, Ltd.	
Metal One Corporation.	
Mitsui & Co., Ltd.	
Miyama Industry Co., Ltd.	
Nakagawa Special Steel Inc.	
Nippon Steel & Sumikin Logistics Co., Ltd.	
Nippon Steel & Sumitomo Metal Corporation.	
Nisshin Steel Co., Ltd.	
Okaya & Co., Ltd.	
Panasonic Corporation.	
Saint-Gobain K.K.	
Shinsho Corporation.	
Sumitomo Corporation.	
Suzukaku Co., Ltd.	
Tokyo Steel Manufacturing Co., Ltd.	
Toyota Tsusho Corporation Nagoya.	
MEXICO: Carbon and Certain Alloy Steel Wire Rod, A–201–830	10/1/17–9/30/18
ArcelorMittal Las Truchas, S.A. de C.V.	
ArcelorMittal Mexico, S.A. de C.V.	
Deacero S.A.P.I. de C.V.	
Grupo Villacero S.A. de C.V.	
Talleres y Aceros S.A. de C.V.	
Ternium Mexico S.A. de C.V.	
POLAND: Emulsion Styrene-Butadiene Rubber,[5] A–455–805	2/24/17–8/31/18
Synthos Dwory 7 Spolka z Ograniczona Odpowiedzialnoscia Spolka Jawna (SP.ZO.O.S.J.)	
REPUBLIC OF KOREA: Certain Hot-Rolled Steel Flat Products, A–580–883	10/1/17–9/30/18
Dongbu Steel Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Hyundai Steel Company.	
Marubeni-Itochu Steel Korea.	
POSCO.	
POSCO Daewoo Corporation.	
Soon Hong Trading Co.	
Sungjin Co.	
REPUBLIC OF KOREA: Emulsion Styrene-Butadiene Rubber,[6] A–580–890	2/24/17–8/31/18
Daewoo International Corporation.	
TAIWAN: Steel Concrete Reinforcing Bar, A–583–859	3/7/17–9/30/18
Lo-Toun Steel and Iron Works Co. Ltd.	
Power Steel Co., Ltd.	
THE NETHERLANDS: Certain Hot-Rolled Steel Flat Products, A–421–813	10/1/17–9/30/18
Tata Steel Ijmuiden BV.	
THE PEOPLE'S REPUBLIC OF CHINA: Freshwater Crawfish Tailmeat,[7] A–570–848	9/1/17–8/31/18
Yancheng Hi-King Agriculture Developing Co., Ltd	
THE PEOPLE'S REPUBLIC OF CHINA: Steel Wire Garment Hangers, A–570–918	10/1/17–9/30/18
Hangzhou Qingqing Mechanical Co., Ltd.	
Hangzhou Yingqing Material Co., Ltd.	
Hong Kong Wells Ltd.	
Shanghai Wells Hanger Co., Ltd.	
TURKEY: Certain Hot-Rolled Steel Flat Products, A–489–826	10/1/17—9/30/18
Agir Haddecilik A.S.	
Cag Celik Demir ve Celik.	
Colakoglu Dis Ticaret A.S.	
Colakoglu Metalurji, A.S.	
Eregli Demir ve Celik Fabrikalari T.A.S.	

	Period to be reviewed
Gazi Metal Mamulleri Sanayi Ve Ticaret A.S.	
Habas Industrial and Medical Gases Production Industries Inc.	
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi.	
Iskenderun Iron & Steel Works Co.	
MMK Atakas Metalurji.	
Ozkan Iron and Steel Ind.	
Seametal San ve Dis Tic.	
Tosyali Holding (Toscelik Profile and Sheet Ind. Co., Toscelik Profil ve Sac).	
TURKEY: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes,[8] A–489–824	9/1/17–8/31/18
Ozdemir Boru Profil San. Ve Tic. Ltd. Sti.	
Countervailing Duty Proceedings	
REPUBLIC OF KOREA: Certain Hot-Rolled Steel Flat Products, C–580–884	1/1/17–12/31/17
DCE Inc.	
Dong Chuel America Inc.	
Dong Chuel Industrial Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dongkuk Industries Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
Hyewon Sni Corporation (H.S.I.).	
Hyundai Steel Company.[9]	
JFE Shoji Trade Korea Ltd.	
POSCO.	
POSCO Coated & Color Steel Co., Ltd.	
POSCO Daewoo Corporation.	
Soon Hong Trading Co., Ltd.	
Sung-A Steel Co., Ltd.	
Suspension Agreements	
RUSSIA: Uranium, A–821–802	10/1/17–9/30/18

[5] The name of the company listed above was misspelled in the initiation notice that published on November 15, 2018 (83 FR 57411). The correct spelling of this company name is listed in this notice.

[6] The name of the company listed above was misspelled in the initiation notice that published on November 15, 2018 (83 FR 57411). The correct spelling of this company name is listed in this notice. In addition, we inadvertently misspelled the name of the product on which the review was initiated. The correct spelling of this product is listed in this notice.

[7] The name of the company listed above was misspelled in the initiation notice that published on November 15, 2018 (83 FR 57411). The correct spelling of this company name is listed in this notice.

[8] The name of the company listed above was misspelled in the initiation notice that published on November 15, 2018 (83 FR 57411). The correct spelling of this company name is listed in this notice. In addition, heavy walled rectangular welded carbon steel pipes and tubes from Turkey produced and exported by Ozdemir Boru Profil San. Ve Tic. Ltd. Sti. was excluded from the antidumping duty order. *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey: Antidumping Duty Orders,* 81 FR 62865 (September 13, 2016). Accordingly, we are initiating this administrative review with respect to Ozdemir Boru Profil San. Ve Tic. Ltd. Sti. only for heavy walled rectangular welded carbon steel pipes and tubes produced in Turkey where Ozdemir Boru Profil San. Ve Tic. Ltd. Sti. acted as either the manufacturer or exporter (but not both).

[9] In their request for review, the petitioners noted that entries for Hyundai Steel Company may also appear under Hyundai Steel Co., Ltd.

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (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). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being

submitted 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. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment.

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information.[10] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty or countervailing duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule*.[11] Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable revised certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by the Secretary. *See* 19 CFR 351.302. In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning U.S. Customs and Border Protection data; and (5) quantity and value questionnaires. Under certain circumstances, Commerce 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, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Please review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: December 6, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–26773 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

[10] *See* section 782(b) of the Act.

[11] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–809]

Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the producers/exporters subject to this review made sales of circular welded non-alloy steel pipe (CWP) from the Republic of Korea (Korea) at less than normal value during the period of review (POR) November 1, 2016, through October 31, 2017. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Mark Kennedy or Peter Zukowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–7883 or (202) 482–0189, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is circular welded non-alloy steel pipe and tube. Imports of the product are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090. While the HTSUS subheadings 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.[1]

Methodology

Commerce conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). Constructed export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 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 *http://access.trade.gov* and to all parties in Commerce's Central Records Unit, located at 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/index.html.*

Preliminary Results of Administrative Review

We preliminarily determine that the following weighted-average dumping

[1] For a full description of the scope of the order, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Circular Welded Non-Alloy Steel Pipe from the Republic of Korea: 2016–2017,'' dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

margins exist for the respondents for the period November 1, 2016, through October 31, 2017:

Producer and/or exporter	Weighted-average dumping margin (percent)
Aju Besteel	10.56
Bookook Steel	10.56
Chang Won Bending	10.56
Dae Ryung	10.56
Daewoo Shipbuilding & Marine Engineering (Dsme)	10.56
Daiduck Piping	10.56
Dong Yang Steel Pipe	10.56
Dongbu Steel	10.56
Eew Korea Company	10.56
Histeel	10.56
Husteel	12.65
Hyundai Rb	10.56
Hyundai Steel (Pipe Divison)	10.56
Hyundai Steel Company	8.47
Kiduck Industries	10.56
Kum Kang Kind	10.56
Kumsoo Connecting	10.56
Miju Steel Mfg	10.56
Nexteel	10.56
Samkang M&T	10.56
Seah Fs	10.56
Seah Steel	10.56
Steel Flower	10.56
Vesta Co., Ltd	10.56
Ycp Co	10.56

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to the parties within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[2] 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.[3]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically *via* ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[4] 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. Commerce will issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

If a respondent's weighted-average dumping margin is above *de minimis* 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 antidumping duties calculated for the importer's examined sales and the total entered value of the sales in accordance with 19 CFR 351.212(b)(1).[5] If the respondent's weighted-average dumping margin is zero or *de minimis* in the final results of reviews, we will instruct U.S. Customs and Border Protection (CBP) not to assess duties on any of its entries in accordance with the *Final Modification for Reviews*.[6]

For entries of subject merchandise during the POR produced by Husteel Co., Ltd. or Hyundai Steel Company for which they did not know their merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

For the 23 companies which were not selected for individual examination, we will instruct CBP to apply the rates listed above to all entries of subject merchandise produced and/or exported by these firms.

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of this review for all shipments of CWP from Korea entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for companies subject to this review will be the rates established in the final results of the review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer is, the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 4.80 percent,[7] the all-others rate established in the less-than-fair-value investigation, adjusted for the export-subsidy rate in the companion countervailing duty investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

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 this POR. 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.

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221(b)(4).

Dated: December 3, 2018.

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

[2] *See* 19 CFR 351.309(d).

[3] *See* 19 CFR 351.309(c)(2) and (d)(2).

[4] *See* 19 CFR 351.310(c).

[5] In these preliminary results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

[6] *See Final Modification for Reviews,* 77 FR at 8102.

[7] *See Notice of Antidumping Duty Orders: Certain Circular Welded Non-Alloy Steel Pipe from Brazil, the Republic of Korea (Korea), Mexico, and Venezuela, and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Non-Alloy Steel Pipe from Korea,* 57 FR 49453 (November 2, 1992).

[FR Doc. 2018–26774 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–523–812]

Circular Welded Carbon-Quality Steel Pipe From the Sultanate of Oman: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that circular welded carbon-quality steel pipe (CWP) from the Sultanate of Oman (Oman) has been sold in the United States at prices below normal value (NV) during the period of review (POR), June 8, 2016, through November 30, 2017. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Dennis McClure or Robert Palmer, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–5973 or (202) 482–9068, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 23, 2018, Commerce initiated the antidumping duty administrative review on circular welded carbon-quality steel pipe from the Sultanate of Oman.[1] This review covers one producer/exporter of the subject merchandise, Al Jazeera Steel Products Co. SAOG (Al Jazeera). For a detailed description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum, dated concurrently with these preliminary results and hereby adopted by this notice.[2]

Scope of the Order

The merchandise subject to the Order [3] is CWP from Oman. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) and (a)(2) of the Tariff Act of 1930, as amended (the Act). Export price was calculated in accordance with section 772 of the Act. NV was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of the topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of the Review

We preliminarily determine that, for the period of June 8, 2016, through November 30, 2017, the following weighted-average dumping margin exists:

Exporter/producer	Weighted-average dumping margin (percent)
Al Jazeera Steel Products Co. SAOG	3.84

Disclosure, Public Comment, and Opportunity To Request a Hearing

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[4] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[5] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), 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.[6] Case and rebuttal briefs should be filed using ACCESS.[7]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Standard Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 8058 (February 23, 2018).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Circular Welded Carbon-Quality Steel Pipe from the Sultanate of Oman; 2016–2017,'' from James P. Maeder, Jr., Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See Circular Welded Carbon-Quality Steel Pipe From the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders,* 81 FR 91906 (December 19, 2016) (the *Order*).

[4] *See* 19 CFR 351.309(c)(1)(ii).

[5] *See* 19 CFR 351.309(d).

[6] *See* 19 CFR 351.309(c)(2) and (d)(2).

[7] *See* 19 CFR 351.303.

Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined.[8] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

We intend to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless the deadline is extended.[9]

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[10]

Pursuant to 19 CFR 351.212(b)(1), as Al Jazeera reported the entered value for its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales. Where the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. We intend to instruct CBP to take into account the ''provisional measures deposit cap,'' in accordance with 19 CFR 351.212(d).

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

In accordance with our ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by Al Jazeera for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate.[11]

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Al Jazeera will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the manufacturer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 7.36 percent, the all-others rate established in the LTFV investigation.[12] These cash deposit requirements, when imposed, shall remain in effect until further notice.

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 this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification To Interested Parties

The preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: December 4, 2018.

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

[FR Doc. 2018–26775 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See* 19 CFR 351.310(c).

[9] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

[10] *See* 19 CFR 351.212(b).

[11] For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[12] *See* the *Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–844]

Steel Concrete Reinforcing Bar From Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Grupo Simec made sales of subject merchandise at less than normal value during the November 1, 2016, through October 31, 2017, period of review (POR), and Deacero S.A.P.I de C.V. (Deacero) did not. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore (Deacero) or Patricia Tran (Grupo Simec), AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone (202) 482–3692 or (202) 482–1503, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 11, 2018, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of the antidumping duty order on steel concrete reinforcing bar (rebar) from Mexico.[1]

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 1329 (January 11, 2018) (*Initiation Notice*).

On March 13, 2018, we selected Deacero and Grupo Simec as mandatory respondents.[2] On July 12, 2018, we issued a memorandum extending the time period for issuing the preliminary results of the instant administrative review from August 6, 2018 to December 3, 2018.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as an Appendix to this notice.

Scope of the Order

Imports covered by the order are shipments of steel concrete reinforcing bar imported in either straight length or coil form (rebar) regardless of metallurgy, length, diameter, or grade. The merchandise subject to review is currently classifiable under items 7213.10.0000, 7214.20.0000, and 7228.30.8010. The subject merchandise may also enter under other Harmonized Tariff Schedule of the United States (HTSUS) numbers including 7215.90.1000, 7215.90.5000, 7221.00.0017, 7221.00.0018, 7221.00.0030, 7221.00.0045, 7222.11.0001, 7222.11.0057, 7222.11.0059, 7222.30.0001, 7227.20.0080, 7227.90.6085, 7228.20.1000, and 7228.60.6000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. Export and constructed export price were calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and is available to all parties in the Central Records Unit, Room B–8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html*. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of the Review

As a result of this review, we calculated a weighted-average dumping margin of 3.70 percent for Grupo Simec and a de minimis margin for Deacero for the period November 1, 2016 through October 31, 2017. Therefore, in accordance with section 735(c)(5)(A) of the Act, we assigned the weighted-average dumping margin of 3.70 percent calculated for Grupo Simec to the nine non-selected companies in these preliminary results, as referenced below.

Producer and/or exporter	Weighted-average dumping margin (percent)
Deacero S.A.P.I de C.V	* 0.00
Grupo Simec (Simec International 6 S.A. de C.V., Orge S.A. de C.V., Aceros Especiales Simec Tlaxcala, S.A. de C.V., Fundiciones de Acero Estructurales, S.A. de C.V., Perfiles Comerciales Sigosa, S.A. de C.V., Operadora de Perfiles Sigosa, S.A. de C.V.)[6]	3.70
Ternium Mexico, S.A. de C.V	3.70
ArcelorMittal Lazaro Cardenas S.A. de C.V	3.70
Cia Siderurgica De California, S.A. de C.V	3.70
AceroMex S.A	3.70
ArcelorMittal Celaya	3.70
ArcelorMittal Cordoba S.A. de C.V	3.70
Siderurgica Tultitlan S.A. de C.V	3.70
Talleres y Aceros, S.A. de C.V	3.70
Grupo Villacero S.A. de C.V	3.70

* (*de minimis*).

Assessment Rate

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for Deacero or Grupo Simec is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[7] If the weighted-average dumping margin for Deacero or Grupo Simec is zero or *de minimis* in the final results, or an importer-specific assessment rate is zero

[2] *See* Memorandum, titled ''Antidumping Duty Administrative Review of Steel Concrete Reinforcing Bar from Mexico; 2016–2017, Selection of Respondents for Individual Examination,'' dated March 13, 2018.

[3] *See* Memorandum, titled ''Antidumping Duty Administrative Review of Steel Concrete Reinforcing Bar from Mexico; 2016–2017 Steel Concrete Reinforcing Bar from Mexico: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review, 2016–2017'' dated July 12, 2018. The memorandum incorrectly stated that the deadline is December 4, 2018; the actual deadline is December 3, 2018.

[4] *See* memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Steel Concrete Reinforcing Bar from Mexico, 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] For a full description of the scope of the order, s*ee* the Preliminary Decision Memorandum.

[6] Commerce previously collapsed Simec International 6 S.A. de C.V. and Orge S.A. de C.V. with Grupo Simec. *See Steel Concrete Reinforcing Bar from Mexico: Final Results of Antidumping Duty Administrative Review; 2014–2015,* 82 FR 27233 (June 14, 2017). In this administrative review, Commerce has preliminarily collapsed Aceros Especiales Simec Tlaxcala, S.A. de C.V., Fundiciones de Acero Estructurales, S.A. de C.V., Perfiles Comerciales Sigosa, S.A. de C.V., Operadora de Perfiles Sigosa, S.A. de C.V. Industrias CH is affiliated with Grupo Simec but Commerce is not collapsing the company into the single entity. *See* Grupo Simec Affiliation and Collapsing Memorandum dated December 3, 2018.

[7] In these preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012). (*Final Modification for Reviews*).

or *de minimis* in the final results, we will instruct CBP not to assess antidumping duties on any of their entries in accordance with the *Final Modification for Reviews*.[8]

In accordance with Commerce's assessment practice, for entries of subject merchandise during the POR produced by each respondent for which it did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for respondents noted above will be the rate established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(I), in which case the cash deposit rate will be zero; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 20.58 percent, the all-others rate established in the antidumping investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed in these preliminary results to parties in this proceeding within five days of the date of publication of this notice.[10]

Public Comment

Pursuant to 19 CFR 351.309(c)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. 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.[11] However, Commerce intends to issue a supplemental questionnaire to Grupo Simec after the preliminary results. Thus, Commerce will subsequently notify parties of the case brief and rebuttal brief deadlines. 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.[12] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, within 30 days after the date of publication of this notice. 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. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

We intend to issue the final results of this administrative review, including the results of our analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

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 this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and increase the subsequent assessment of the antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: December 3, 2018.

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

[FR Doc. 2018–26770 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

[8] *Id.* at 8102.

[9] *See Steel Concrete Reinforcing Bar from Mexico: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 79 FR 54967 (September 15, 2014).

[10] *See* 19 CFR 351.224(b).

[11] *See* 19 CFR 351.309(d).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–837]

Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Final Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Nan Ya Plastics Corporation (Nan Ya) did not sell subject merchandise at less than normal value during the POR, July 1, 2016 through June 30, 2017.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2018, Commerce published the preliminary results for this administrative review.[1] We invited interested parties to comment on the *Preliminary Results*. We received no comments nor requests for a hearing from any party.[2] Commerce conducted this administrative review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the antidumping duty order are all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip (PET film), whether extruded or coextruded. Excluded are metalized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of PET film are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the antidumping duty order is dispositive.

Final Determination of No Shipments

Based on our analysis of U.S. Customs and Border Protection (CBP) information and information provided by Shinkong Materials Technology Corporation (SMTC) and its affiliate Shinkong Synthetic Fibers Corporation (SSFC), we determine that SMTC had no shipments of the subject merchandise during the POR.

Final Results of Review

As there are no changes from, or comments upon, the *Preliminary Results,* Commerce has not modified its analysis or calculations. Accordingly, no decision memorandum accompanies this **Federal Register** notice. We continue to find that Nan Ya did not make sales of subject merchandise at less than normal value during the POR.

Commerce determines that the weighted-average dumping margin exists for the period July 1, 2016, through June 30, 2017:

Producer/exporter	Weighted-average margin (percentage)
Nan Ya Plastics Corporation	0.00

Assessment Rates

Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries in this review, in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1). Commerce intends to issue assessment instructions directly to CBP 15 days after publication of these final results of review. Because we calculated a zero margin in the final results of this review for Nan Ya, in accordance with 19 CFR 351.212, we will instruct CBP to liquidate the appropriate entries without regard to dumping duties.

In accordance with Commerce's practice, for entries of subject merchandise during the POR that SMTC or its affiliate, SSFC, did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Nan Ya will be 0.00 percent, the rate established in the final results of this review; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this or any previous review or in the original less-than-fair-value (LTFV) investigation but the manufacturer is, the cash-deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review or the investigation, the cash-deposit rate will continue to be the all-others rate of 2.40 percent, which is the all-others rate established by Commerce in the LTFV investigation.[3] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final 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 this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested.

[1] *See Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017,* 83 FR 39687. (August 10, 2018) (*Preliminary Results*) and accompanying Preliminary Issues and Decision Memorandum.

[2] For further details of the issues addressed in this proceeding, *see* the *Preliminary Results* and accompanying Preliminary Issues and Decision Memorandum.

[3] *See Notice of Final Amended Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet and Strip (PET) from Taiwan,* 67 FR 44174 (July 1, 2002); *see also Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 67 FR 46566 (July 15, 2002).

Failure to comply with the regulations and terms of an APO is a violation, which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: December 4, 2018.

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.

[FR Doc. 2018–26777 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–826]

Monosodium Glutamate From the Republic of Indonesia: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that PT. Cheil Jedang Indonesia (CJ Indonesia), the sole respondent in this administrative review, made sales of subject merchandise in the United States at prices below normal value during the period of review covering November 1, 2016, through October 31, 2017 (POR). Commerce is also rescinding the administrative review with respect to PT. Miwon Indonesia (Miwon). We invite interested parties to comment on these preliminary results.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Gene H. Calvert, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On January 11, 2018, based on requests from interested parties, Commerce initiated the administrative review on monosodium glutamate (MSG) from the Republic of Indonesia (Indonesia) covering Miwon and CJ Indonesia.[1] A detailed description of the events that followed the initiation of this review can be found in the Preliminary Decision Memorandum.[2] This administrative review is being conducted in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The product covered by this review is MSG from Indonesia. A complete description of the scope of the order can be found in the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. The notice initiating the instant administrative review was published on January 11, 2018. On April 4, 2018, Daesang America, Inc. (Daesang), a U.S. importer of MSG from Indonesia, timely withdrew its request for an administrative review with respect to Miwon.[3] Because Daesang timely withdrew its request for an administrative review of Miwon within 90 days of the date of publication of the *Initiation Notice,* and as there are no remaining requests to review Miwon, Commerce is rescinding this review with respect to Miwon, in accordance with 19 CFR 351.213(d)(1).

Methodology

Commerce is conducting this administrative review in accordance with sections 751(a)(1)(B) and (2) of the Act. Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. A full description of the methodology underlying these preliminary results can be found in the Preliminary Determination Memorandum. A list of the topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Duty Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and its electronic version are identical in content.

Preliminary Results of Review

Commerce preliminarily determines that a weighted-average margin of 24.68 percent exists for CJ Indonesia for the period November 1, 2016, through October 31, 2017.

Assessment Rates

Upon issuance of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[4]

If the weighted-average dumping margin for CJ Indonesia is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific ad valorem antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.5 percent). If the respondent's (*i.e.,* CJ Indonesia's) weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review where applicable.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by CJ Indonesia for which the producer did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate entries not reviewed at the all-others rate if there is no rate for the

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 1329 (January 11, 2018) (*Initiation Notice*).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Monosodium Glutamate from the Republic of Indonesia; 2016–2017,'' (Preliminary Decision Memorandum), which is dated concurrently with, and hereby adopted by, this notice.

[3] *See* Letter from Daesang, ''Monosodium Glutamate from Indonesia: Requesting Rescission of Administrative Review—PT. Miwon, Indonesia,'' dated April 4, 2018.

[4] *See* 19 CFR 351.212(b).

intermediate company (or companies) involved in the transaction.[5] We intend to issue appropriate instructions to CBP 15 days after the date of publication of the final results of this review.

For the company for which this review is rescinded (*i.e.,* Miwon), antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions with respect to the company for which this review is being rescinded to CBP 15 days after the publication of this notice.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for CJ Indonesia will be the rate established in the final results of this review, except if the rate is less than 0.5 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value (LTFV) investigation, but the manufacturer is covered in this review, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 6.19 percent, the all-others rate established in the LTFV investigation.[6] These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose to interested parties the calculations performed in reaching these preliminary results within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit written comments (case briefs) at a date to be determined by Commerce and rebuttal comments (rebuttal briefs) within five days after the time limit for filing case briefs.[7] Rebuttal briefs must be limited to issues raised in the case briefs.[8] Commerce will notify interested parties when it has determined a deadline for case briefs. Parties who submit case or rebuttal briefs are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[9]

Interested parties who wish to request a hearing must do so within 30 days of publication of these preliminary results by submitting a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, using Enforcement and Compliance's ACCESS system.[10] Hearing requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing, which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230, at a time and location to be determined.[11] Parties should confirm by telephone the date, time, and location of the hearing. Issues addressed at the hearing will be limited to those raised in the briefs.[12] All briefs and hearing requests must be filed electronically and received successfully in their entirety through ACCESS by 5:00 p.m. Eastern Time by their respective deadlines.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless otherwise extended.[13]

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: December 3, 2018.

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

[FR Doc. 2018–26772 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818]

Certain Pasta From Italy: Final Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Ghigi 1870 S.p.A. and Pasta Zara S.p.A. (collectively, Ghigi/Zara) sold pasta

[5] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[6] *See Monosodium Glutamate from the People's Republic of China, and the Republic of Indonesia: Antidumping Duty Orders; and Monosodium Glutamate from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 70505 (November 26, 2014).

[7] *See* 19 CFR 351.309(c)(l)(ii) and 351.309(d)(l). Interested parties will be notified through ACCESS regarding the deadline for submitting case briefs.

[8] *See* 19 CFR 351.309(d)(2).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] *See* 19 CFR 351.310(c).

[11] *See* 19 CFR 351.310.

[12] *See* 19 CFR 351.310(c).

[13] *See* section 751(a)(3)(A) of the Act.

from Italy at less than normal value (NV) during the period of review (POR) July 1, 2016, through June 30, 2017, but Industria Alimentare Colavita S.p.A. (Indalco) did not.

DATES: Applicable December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Joy Zhang (Ghigi/Zara) or George McMahon (Indalco), AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1168 or (202) 482–1167, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* on August 10, 2018.[1] For events subsequent to the *Preliminary Results, see* Commerce's Issues and Decision Memorandum.[2]

Scope of the Order

Imports covered by the order are shipments of certain non-egg dry pasta. The merchandise subject to review is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.[3]

Analysis of Comments Received

In the Issues and Decision Memorandum, we addressed all issues raised in parties' case and rebuttal briefs. In the Appendix to this notice, we provide a list of the issues raised by parties. The Issues and Decision Memorandum is a public document and is on-file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and in the Central Records Unit (CRU), Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html*. The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties, these final results do not differ from the *Preliminary Results* with respect to Ghigi/Zara, Indalco, and the seven firms not subject to individual review.[4]

Final Results of the Review

As a result of this review, Commerce calculated a weighted-average dumping margin that is above *de minimis* for Ghigi/Zara and a zero margin for Indalco for the POR. Therefore, consistent with its practice and the methodology set forth in section 735(c)(5)(A) of the Tariff Act of 1930, as amended (the Act), Commerce assigned the weighted-average dumping margin calculated for Ghigi/Zara to the seven non-selected companies in these final results, as referenced below.

Producer and/or exporter	Weighted-average dumping margin (percent)
Ghigi 1870 S.p.A. and Pasta Zara S.p.A. (Zara) (collectively Ghigi/Zara)	5.97
Industria Alimentare Colavita S.p.A. (Indalco)	0.00
Agritalia S.r.L. (Agritalia)	5.97
Alessio, Panarese Soceieta Agricola (Alessio)	5.97
Antico Pastificio Morelli 1860 S.r.l. (Antico)	5.97
Colussi SpA (Colussi)	5.97
Liguori Pastificio dal 1820 S.p.A. (Liguori)	5.97
Pastificio Menucci SpA (Menucci)	5.97
Tesa SrL (Tesa)	5.97

Duty Assessment

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce shall determine and Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries.[5] For any individually examined respondent whose weighted-average dumping margin is above *de minimis,* we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). Upon issuance of the final results of this administrative review, if any importer-specific assessment rates calculated in the final results are above *de minimis* (*i.e.,* at or above 0.5 percent), Commerce will issue instructions directly to CBP to assess antidumping duties on appropriate entries. Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

In accordance with Commerce's ''automatic assessment'' practice,[6] for entries of subject merchandise during the POR produced by each respondent for which it did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

We intend to issue assessment instructions directly to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for respondents noted above will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most

[1] *See Certain Pasta from Italy: Preliminary Results of Antidumping Duty Administrative Review;* 2016–2017, 83 FR 39685 (August 10, 2018) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Certain Pasta from Italy: Issues and Decision Memorandum for the Final Results; 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Issues and Decision Memorandum for a complete description of the scope of the Order.

[4] The seven companies not subject to individual review are listed in the ''Final Results of Review'' section below.

[5] In these final results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[6] For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

recently completed segment of this proceeding for the manufacturer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 15.45 percent, the all-others rate established in the antidumping investigation as modified by the section 129 determination. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: December 4, 2018.

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 Final Issues and Decision Memorandum

[FR Doc. 2018–26771 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Greater Atlantic Region Surfclam and Ocean Quahog ITQ Administration.

OMB Control Number: 0648–0240.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 177.

Average Hours per Response:: ITQ permit application form, review of a pre-filled form for renewing entities, ITQ transfer form, 5 minutes each; 1 hour to complete the ITQ ownership form for new applicants and 30 minutes for the application to shuck surfclams and ocean quahogs at sea. The requirements under the PSP protocol are based on the number of vessels that land surfclams or ocean quahogs and the number of trips taken into the area, with a total estimated annual burden of 3 hours per vessel.

Burden Hours: 2,473.

Needs and Uses: This request is for an extension of a currently approved collection associated with the Atlantic surfclam and ocean quahog fisheries. National Marine Fisheries Service (NMFS) Greater Atlantic Region manages these fisheries in the Exclusive Economic Zone (EEZ) of the Northeastern United States through the Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP). The Mid-Atlantic Fishery Management Council prepared the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The regulations implementing the FMP are specified at 50 CFR part 648.

The recordkeeping and reporting requirements at §§ 648.74, 648.75, and 648.76 form the basis for this collection of information. We request information from surfclam and ocean quahog individual transferable quota (ITQ) permit holders to issue ITQ permits and to process and track requests from permit holders to transfer quota share or cage tags. We also request information from surfclam and ocean quahog ITQ permit holders to track and properly account for surfclam and ocean quahog harvest shucked at sea. Because there is not a standard conversion factor for estimating unshucked product from shucked product, NMFS requires vessels that shuck product at sea to carry on board the vessel a NMFS-approved observer to certify the amount of these clams harvested. This information, upon receipt, results in an efficient and accurate database for management and monitoring of fisheries of the Northeastern U.S. EEZ.

Georges Bank has been closed to the harvest of surfclams and ocean quahogs since 1990 due to red tide blooms that cause paralytic shellfish poisoning (PSP). We reopened a portion of the Georges Bank Closed Area starting in 2012 under certain conditions. We request information from surfclam and ocean quahog ITQ permit holders who fish in the reopened area to ensure compliance with the Protocol for Onboard Screening and Dockside Testing in Molluscan Shellfish. The U.S. Food and Drug Administration, the commercial fishing industry, and NMFS developed the PSP protocol to test and verify that clams harvested from Georges Bank continue to be safe for human consumption. The National Shellfish Sanitation Program adopted the PSP protocol at the October 2011 Interstate Shellfish Sanitation Conference.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of

Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: December 5, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–26752 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Southeast Region Vessel Monitoring System and Related Requirements.

OMB Control Number: 0648–0544.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 945.

Average Hours per Response: Power-down exemption requests, 5 minutes; transmission of fishing activity reports, 1 minute; and annual maintenance, 2 hours.

Burden Hours: 2,725.

Needs and Uses: This request is for an extension of a currently approved information collection.

The Magnuson-Stevens Fishery Conservation and Management Act authorizes the Gulf of Mexico Fishery Management Council (Gulf Council) and South Atlantic Fishery Management Council (South Atlantic Council) to prepare and amend fishery management plans for any fishery in Federal waters under their respective jurisdictions. NMFS and the Gulf Council manage the reef fish fishery in the Gulf of Mexico (Gulf) under the Fishery Management Plan (FMP) for Reef Fish Resources of the Gulf of Mexico. NMFS and the South Atlantic Council manage the fishery for rock shrimp in the South Atlantic under the FMP for the Shrimp Fishery in the South Atlantic Region. The vessel monitoring system (VMS) regulations for the Gulf reef fish fishery and the South Atlantic rock shrimp fishery may be found at 50 CFR 622.28 and 622.205, respectively.

The FMPs and the implementing regulations contain several specific management areas where fishing is restricted or prohibited to protect habitat or spawning aggregations, or to control fishing pressure. Unlike size, bag, and trip limits, where the catch can be monitored on shore when a vessel returns to port, area restrictions require at-sea enforcement. However, at-sea enforcement of offshore areas is difficult due to the distance from shore and the limited number of patrol vessels, resulting in a need to improve enforceability of area fishing restrictions through remote sensing methods. In addition, all fishing gears are subject to some area fishing restrictions. Because of the sizes of these areas and the distances from shore, the effectiveness of enforcement through over flights and at-sea interception is limited. An electronic VMS allows a more effective means to monitor vessels for intrusions into restricted areas.

The VMS provides effort data and significantly aids in enforcement of areas closed to fishing. All position reports are treated in accordance with NMFS existing guidelines for confidential data. As a condition of authorized fishing for or possession of Gulf reef fish or South Atlantic rock shrimp in or from Federal waters, vessel owners or operators subject to VMS requirements must allow NMFS, the United States Coast Guard, and their authorized officers and designees, access to the vessel's position data obtained from the VMS.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: On occasion and at least hourly for VMS.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: December 5, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–26751 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Transshipment Requirements under the WCPFC.

OMB Control Number: 0648–0649.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 222.

Average Hours per Response: Transshipment Report: 60 minutes; Notice for Transshipment: 15 minutes; Pre-trip Notification for Observer Placement: 1 minute; Purse Seine Discard Report: 30 minutes; Purse Seine Fishing Activity Information: 10 minutes.

Burden Hours: 2,142.

Needs and Uses: This request is for an extension of a currently approved information collection.

National Marine Fisheries Service (NMFS) has issued regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFCIA; 16 U.S.C. 6901 *et seq.*) to carry out the obligations of the United States under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention). The regulations include requirements for the owners and operators of U.S. vessels to: (1) Complete and submit a Pacific Transshipment Declaration form for each transshipment of highly migratory species in the area of application of the Convention (Convention Area) and each transshipment of highly migratory species caught in the Convention Area; (2) submit a notice containing specific information at least 36 hours prior to each transshipment on the high seas in the Convention Area or within 12 hours of an emergency transshipment that would otherwise be prohibited; (3) provide notice to NMFS at least 72 hours before leaving port of the need for an observer, in the event that a vessel anticipates a transshipment where an observer is required; (4) complete and submit a U.S. Purse Seine Discard form

within 48 hours after any discard; and (5) submit certain information regarding purse seine fishing activities.

The information collected from these requirements is used by NOAA and the WCPFC to help ensure compliance with domestic laws and the Commission's conservation and management measures, and are necessary in order for the United States to satisfy its obligations under the Convention.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: December 5, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–26753 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG653

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice; re-opening of public comment period.

SUMMARY: The National Marine Fisheries Service (NMFS) is announcing the re-opening of a public comment period regarding recreational fisheries in the State of Idaho. The FMEP, provided by the Idaho Department of Fish and Game (IDFG), specifies the implementation of fisheries targeting adipose-fin-clipped, hatchery-origin Snake River steelhead within the State of Idaho and in boundary waters with Oregon and Washington. On November 6, 2018, NMFS opened a 30-day public comment period on a Fishery Management and Evaluation Plan (FMEP) pursuant to the protective regulations promulgated for Pacific salmon and steelhead under the Endangered Species Act (ESA). That comment period ended on December 6, 2018. In response to a request received from the public, NMFS intends to obtain additional information.

DATES: Comments must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5:00 p.m. Pacific time on December 13, 2018.

ADDRESSES: Written comments on the application should be addressed to the NMFS Sustainable Fisheries Division, 1201 NE Lloyd Boulevard, Suite 1100, Portland, OR 97232. Comments may be submitted by email. The mailbox address for providing email comments is: *IdahoSteelheadFisheriesPlan.wcr@noaa.gov.* Include in the subject line of the email comment the following identifier: Idaho's Snake River Steelhead Fisheries Plan.

FOR FURTHER INFORMATION CONTACT: Allyson Purcell, at phone number: (503) 736–4736, or via email: *allyson.purcell@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): threatened, naturally produced and artificially propagated Snake River Spring/Summer and Snake River Fall.

Steelhead (*O. mykiss*): threatened, naturally produced and artificially propagated Snake River Basin.

Sockeye salmon (*O. nerka*): endangered, naturally produced and artificially propagated Snake River.

IDFG submitted the FMEP to NMFS describing fisheries targeting adult adipose-fin-clipped, hatchery-origin steelhead within the State of Idaho and in boundary waters with Oregon and Washington. The plan was submitted under ESA limit 4 of the 4(d) Rule. These fisheries were designed to support fishing opportunities while minimizing potential risks to ESA-listed species. The FMEP describes timing, location, harvest impact limits, licensing, and gear requirements, and requires that all fish caught with an intact adipose fin be released unharmed. A variety of monitoring and evaluation is included in the FMEP.

This reopening is in place of a planned extension of the comment period. NMFS had previously considered extending the comment period by seven days, until December 13. However, extensions may only occur while the comment period is ongoing, and NMFS could not be certain that a public notice of an extension would be published before December 6. Therefore, to avoid potential confusion, we are executing a reopening of the comment period to accept comments until December 13, so that the result is identical to the planned extension. This additional period for public comment will not affect NMFS's overall schedule for completing our ESA review.

As specified in the July 10, 2000, ESA 4(d) rule for salmon and steelhead (65 FR 42422) and updated June 28, 2005 (70 FR 37160), NMFS may approve an FMEP if it meets criteria set forth in 50 CFR 223.203(b)(4)(i)(A) through (I). Prior to final approval of an FMEP, NMFS must publish notification announcing the FMEP's availability for public review and comment.

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 4 of the updated 4(d) rule (50 CFR 223.203(b)(4)) further provides that the prohibitions of paragraph (a) of the updated 4(d) rule (50 CFR 223.203(a)) do not apply to fisheries provided that an FMEP has been approved by NMFS to be in accordance with the salmon and steelhead 4(d) rule (65 FR 42422, July 10, 2000, as updated in 70 FR 37160, June 28, 2005).

Dated: December 6, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–26794 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE766

Marine Mammals; File No. 20532

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

ACTION: Notice; receipt of application for permit amendment.

SUMMARY: Notice is hereby given that Stephen John Trumble, Ph.D., Baylor University, 101 Bagby Ave, Waco, TX 76706, has applied in due form for an amendment to Scientific Research Permit No. 20532 for the import, export,

and receipt of marine mammal parts for scientific research.

DATES: Written, telefaxed, or email comments must be received on or before January 10, 2019.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 20532 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. 20532 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan or Jennifer Skidmore, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 20532 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 20532, issued on October 26, 2016 (81 FR 70100), authorizes the permit holder to receive, import, and export biological samples from seven species of cetaceans from museum holdings, stranded animals, or legally subsistence hunted animals worldwide for scientific research to chronologically profile anthropogenic and physiological data including hormones and pesticides to record exposure and stress. The permit holder is requesting the permit be amended to include authorization to import earwax and baleen samples from additional cetacean species including: 50 each of Bryde's (*Balaenoptera edeni*), all species of right (*Eubalaena* spp.), and sei (*Balaenoptera borealis*) whales, and up to 100 individual unidentified cetaceans.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the applications to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: December 6, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–26749 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the NOAA Science Advisory Board (SAB). The members will discuss issues outlined in the section on Matters to be considered.

DATES: The meeting will be held Wednesday, February 27, 2019 from 1:00 p.m. EST to 4:00 p.m. EST. These times and agenda topics described below are subject to change. For the latest agenda please refer to the SAB website: *http://sab.noaa.gov/SABMeetings.aspx*.

ADDRESSES: The meeting will be held at the Hugh Gregg Coastal Conservation Center, 93 Depot Road, Greenland, NH 03840. Members of the public may participate virtually by registering at: *https://attendee.gotowebinar.com/register/3113875598632844289*.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, SSMC3, Room 11230, 1315 East-West Hwy., Silver Spring, MD 20910; Phone Number: 301–734–1156; Email: *Cynthia.Decker@noaa.gov;* or visit the SAB website at *http://sab.noaa.gov/SABMeetings.aspx*.

SUPPLEMENTARY INFORMATION: The NOAA Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Matters to be Considered: The meeting will include the following topics: (1) Climate Working Group Review of the Climate Program Office Climate and Global Change Post-Doctoral Program; (2) Environmental Information Services Working Group Interim Report on the Use of Observing System Simulation Experiments (OSSEs); (3) Input on the draft NOAA Strategic Aquaculture Science Plan; and (4) Discussion of the NOAA Research and Development Plan. Meeting materials, including work products will be made available on the SAB website: *http://sab.noaa.gov/SABMeetings.aspx*.

Status: The meeting will be open to public participation with a 5-minute public comment period on February 27th from 3:50–3:55 p.m. EST (check website to confirm time). The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of one (1) minute. Written comments for the meeting should be received in the SAB Executive Director's Office by February 20, 2019 to provide sufficient time for SAB review. Written comments received after February 20 will be distributed to the SAB, but may not be reviewed prior to the meeting date. Seating at the meeting will be available on a first-come, first served basis.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for special accommodations may be directed no later than 12:00 p.m. on February 20, 2019, to Dr. Cynthia Decker, SAB Executive Director, SSMC3, Room 11230, 1315 East-West Highway, Silver Spring, MC 20910; Email: *Cynthia.Decker@noaa.gov*.

Dated: November 27, 2018.

Eric Locklear,

Deputy Chief Financial Officer/ Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2018–26786 Filed 12–10–18; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Intent To Grant Exclusive Patent License to H2 Power, LLC; Chicago, IL

AGENCY: Department of the Army, DoD.

ACTION: Notice of intent.

SUMMARY: The Department of the Army hereby gives notice of its intent to grant to H2 Power, LLC; a corporation having its principle place of business at 333 North Michigan Avenue, Suite 1117, Chicago, IL 60601, an exclusive license.

DATES: Written objections must be filed not later than 15 days following publication of this announcement.

ADDRESSES: Send written objections to U.S. Army Research Laboratory, Technology Transfer and Outreach Office, RDRL–DPT/Annmarie Martin, Building 321, Room 126, 6375 Johnson Rd., Aberdeen Proving Ground, MD 21005–5425.

FOR FURTHER INFORMATION CONTACT: Annmarie Martin, (410) 278–9106, email: *ORTA@arl.army.mil.*

SUPPLEMENTARY INFORMATION: The Department of the Army plans to grant an exclusive license to H2 Power, LLC related to ''Aluminum based nanogalvanic compositions useful for generating hydrogen gas and low temperature processing thereof'', U.S. Patent Application No.: 16/042632, Filing Date July, 2018 in the fields of use related to;

—Automotive & Transportation power generation applications related to 2/3/4/6 wheeled vehicles, such as motorcycles, all sizes of cars, mini-vans, van, SUV, pick-up truck, panel truck, other light and medium trucks up to 26,000lbs, and any size bus, and

—Power generation applications via generators and micro-grid equipment that generate 15kW and above.

The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the U.S. Army Research Laboratory receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). Competing applications completed and received by the U.S. Army Research Laboratory within fifteen (15) days from the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2018–26761 Filed 12–10–18; 8:45 am]

BILLING CODE 5001–03–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2018–OS–0024]

Manual for Courts-Martial; Publication of Supplementary Materials

AGENCY: Joint Service Committee on Military Justice (JSC), Department of Defense.

ACTION: Publication of discussion and analysis (supplementary materials) accompanying the Manual for Courts-Martial, United States (2019 ed.) (MCM).

SUMMARY: The JSC hereby publishes Supplementary Materials accompanying the MCM as amended by Executive Order 13825. These changes have not been coordinated within the Department of Defense under DoD Directive 5500.1, ''Preparation, Processing and Coordinating Legislation, Executive Orders, Proclamations, Views Letters and Testimony,'' June 15, 2007, and do not constitute the official position of the Department of Defense, the Military Departments, or any other Government agency. These Supplementary Materials have been approved by the JSC and the General Counsel of the Department of Defense, and shall be applied in conjunction with the rule with which they are associated. The Discussions are effective insofar as the Rules they supplement are effective, but may not be applied earlier than the date of publication in the **Federal Register**.

DATES: These Supplementary Materials are effective as of January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Jennifer Luce, JAGC, USN (202) 685–7058 or *jennifer.luce@navy.mil.* The JSC website is located at: *http://jsc.defense.gov.*

SUPPLEMENTARY INFORMATION:

Public Comments: The JSC solicited public comments for these supplementary materials via the **Federal Register** on July 11, 2017 (82 FR 31952–31953, Docket ID: DoD–2017–OS–0032), held a public meeting on August 3, 2017, and published the JSC response to public comments via the **Federal Register** on May 23, 2018 (83 FR 23907–23908, Docket ID: DoD–DoD–2018–OS–0024).

Due to the length of the changes, they are being made available on the internet rather than being printed in the **Federal Register**. The supplementary materials are available at *http://jsc.defense.gov.*

Dated: November 30, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–26787 Filed 12–10–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0130]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; State Charter School Facilities Incentive Grants Program (1894–0001)

AGENCY: Office of Innovation and Improvement (OII), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before January 10, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0130. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance

Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9089, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Clifton Jones, 202–205–2204.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: State Charter School Facilities Incentive Grants Program (1894–0001).

OMB Control Number: 1855–0012.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 12.

Total Estimated Number of Annual Burden Hours: 480.

Abstract: The State Charter School Facilities Incentive Grants Program allows States to apply for Federal assistance. These grants are made to States to provide them with an incentive to create new or enhance existing per-pupil facilities aid programs for charter schools. The applicants will provide a description of their proposed activities and provide information necessary to determine which grant applications should be funded. An additional part of the application consists of assurances regarding the applicant's compliance with applicable Federal laws and regulations. The information provided in the application will allow field readers and the Department of Education to determine if applicants are eligible and identify which applications most merit funding.

Dated: December 6, 2018.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–26783 Filed 12–10–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Proposed Agency Information Collection

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995.

DATES: Comments regarding this proposed information collection must be received on or before January 10, 2019. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Jay Wrobel, EE–5A/Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, by fax at (202) 586–9234, or by email at *chp@ee.doe.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Jay Wrobel, EE–5A/Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, by fax at (202) 586–9234, or by email at *chp@ee.doe.gov*.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) 1910–NEW;

(2) *Information Collection Request Title:* Combined Heat and Power (CHP) Packaged System e-Catalog (e-Catalog);

(3) T*ype of Request:* New.

(4) *Purpose:* DOE's ''CHP Technical Potential in the U.S.'' shows significant technical potential in commercial buildings and industrial facilities in the < 10MW size range. Due to building characteristic similarities, this size range is particularly disposed to standardization of CHP systems. The e-Catalog creates a mechanism to take advantage of this standardization including the risk and cost reduction that are expected to ensue. This request for information consists of a voluntary data collection process for e-Catalog participation: to enroll CHP packagers and CHP solutions providers; develop an e-Catalog of packaged CHP systems; and relay the benefits of packaged CHP system performance to industry. Typical respondents are expected to be CHP project developers, CHP designers and packagers, and state and local energy program offices. Each respondent should have experience with compiling the data requested. Participation in the e-Catalog is voluntary, and it is expected that respondents would already have access to the information requested in this collection.

There are four types of information to be collected from primary participants: (1) Background data, including contact information and basic information about the CHP packager's experience with CHP design, durability and performance testing—collected in the CHP Packager Enrollment Form; (2) Background data, including contact information and basic information about the CHP solutions provider's experience with CHP design, durability and performance testing, installation, operation and maintenance—collected in the CHP Solutions Provider Enrolment Form; (3) contact information and program description of market engagement programs that support Packaged CHP systems—collected in the Market Engagement Registration Form; and (4) Information, including packaged system component descriptions, design data, full-load and part-load performance data at three ambient conditions—collected in Packaged CHP System Application Form; Background data will primarily be used as a means to recognize CHP packers and solution providers, and establish the e-Catalog.

(5) *Annual Estimated Number of Respondents:* 50;

(6) *Annual Estimated Number of Total Responses:* 177;

(7) *Annual Estimated Number of Burden Hours:* 739;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $30,506.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the

methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Statutory Authority: Energy Policy Act of 2005 sec 911—Energy Efficiency and sec 106 Voluntary Commitments to Reduce Industrial Energy Intensity.

Issued in Washington, DC on December 4, 2018.

Rob Ivester,

Director, Advanced Manufacturing Office, CHP Deployment Program.

[FR Doc. 2018–26776 Filed 12–10–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 14–179–LNG]

Notice of Change in Control; Pieridae Energy (USA) Ltd.

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of change in control.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of a Notice of Change in Control (Notice) filed by Pieridae Energy (USA) Ltd. (Pieridae US) in the above-referenced docket on August 31, 2018. The Notice describes a change in control of Pieridae Energy Limited, the parent company of Pieridae US.

DATES: Protests, motions to intervene or notices of intervention, as applicable, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, December 26, 2018.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Regular Mail: U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Larine Moore or Amy Sweeney, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9478; (202) 586–2627.

Cassandra Bernstein, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793.

SUPPLEMENTARY INFORMATION:

Summary of Change in Control

The Notice was filed under section 3 of the Natural Gas Act (NGA), 15 U.S.C. 717b. Pieridae US filed a Notice of Change in Control in the above-referenced docket on August 31, 2018.[1] In the Notice, Pieridae US states that it is wholly-owned by Pieridae Energy Limited (Pieridae). Pieridae US further states that, during July 2018, Electron Capital Partners, LLC (a Delaware corporation), either alone or together with Electron Global Master Fund, L.P. (collectively, Electron) acquired beneficial ownership of, or exercised control or direction over, 10% or more of all issued and outstanding common shares of Pieridae. As of July 31, 2018, Electron beneficially owned, or exercised control or direction over, 7,127,775 common shares of Pieridae, representing approximately 14.1% of Pieridae's issued and outstanding common shares.[2]

Additional details can be found in the Notice, posted on the DOE/FE website at: *https://www.energy.gov/sites/prod/files/2018/09/f55/CIC%2008_31_18.pdf.*

DOE/FE Evaluation

DOE/FE will review Pieridae US's Notice in accordance with its Procedures for Changes in Control Affecting Applications and Authorizations to Import or Export Natural Gas (CIC Procedures).[3] Consistent with the CIC Procedures, this notice addresses only the proceeding in which Pieridae US has been granted final authorization to export liquefied natural gas (LNG) to countries with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas (non-FTA countries). The affected proceeding is FE Docket No. 14–179–LNG. If no interested person protests the change in control and DOE takes no action on its own motion, the change in control will be deemed granted 30 days after publication in the **Federal Register**. If one or more protests are submitted, DOE will review any motions to intervene, protests, and answers, and will issue a determination as to whether the proposed change in control has been demonstrated to render the underlying authorization inconsistent with the public interest.

Public Comment Procedures

Interested persons will be provided 15 days from the date of publication of this notice in the **Federal Register** in order to move to intervene, protest, and answer Pieridae US's Notice. Protests, motions to intervene, notices of intervention, and written comments are invited only as to the change in control described in the Notice.[4] All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by DOE's regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Preferred method: emailing the filing to *fergas@hq.doe.gov,* with the individual FE Docket Number(s) in the title line, or Pieridae Change in Control in the title line to include all applicable dockets in this Notice; (2) mailing an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation, Analysis, and Engagement at the address listed in **ADDRESSES**. All filings must include a reference to the individual FE Docket Number(s) in the title line, or Pieridae Change in Control in the title line to include all applicable dockets in this Notice. *Please Note:* If submitting a filing via email, please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of

[1] Pieridae Energy (USA) Ltd., FE Docket No. 14–179–LNG, Notice of Change in Control (Aug. 31, 2018).

[2] Pieridae US is advised that its described change in control may also require the approval of the Committee on Foreign Investment in the United States (CFIUS). DOE expresses no opinion regarding the need for review by CFIUS. Additional information may be obtained at: *https://home.treasury.gov/policy-issues/international/the-committee-on-foreign-investment-in-the-united-states-cfius.*

[3] 79 FR 65541 (Nov. 5, 2014).

[4] Intervention, if granted, would constitute intervention only in the change in control portion of this proceeding, as described herein.

the filing, a digital copy on disk of the entire submission.

The Notice and any filed protests, motions to intervene or notice of interventions, and comments are available for inspection and copying in the Office of Regulation, Analysis, and Engagement docket room, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The Notice and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Signed in Washington, DC, on December 6, 2018.

Amy Sweeney,

Director, Division of Natural Gas Regulation.

[FR Doc. 2018–26763 Filed 12–10–18; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[9986–19–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Kansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Kansas' request to revise/modify certain of its EPA-authorized programs to allow electronic reporting.

DATES: EPA approves the authorized program revisions/modifications as of December 11, 2018.

FOR FURTHER INFORMATION CONTACT: Devon Martin, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2824T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–2603, *martin.devon@epa.gov*.

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On September 11, 2018, the Kansas Department of Health and Environment (KDHE) submitted an application titled ''Kansas Environmental Information Management System'' for revisions/modifications to its EPA-approved programs under title 40 CFR to allow new electronic reporting. EPA reviewed KDHE's request to revise/modify its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Kansas' request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR parts 50–52, 60–65, and 70, is being published in the **Federal Register**:

Part 52—Approval and Promulgation of Implementation Plans;

Part 60—Standards of Performance For New Stationary Sources;

Part 62—Approval and Promulgation of State Plans for Designated Facilities and Pollutants;

Part 63—National Emission Standards for Hazardous Air Pollutants for Source Categories; and

Part 70—State Operating Permit Programs.

KDHE was notified of EPA's determination to approve its application with respect to the authorized programs listed above.

Matthew Leopard,

Director, Office of Information Management.

[FR Doc. 2018–26731 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0030; FRL–9986–33–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Metallic Mineral Processing Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Metallic Mineral Processing Plants (EPA ICR Number 0982.12, OMB Control Number 2060–0016), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2018. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 10, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0030, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats,

information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for Metallic Mineral Processing Plants (40 CFR part 60, subpart LL) apply to the following facilities at metallic mineral processing plants: Each crusher and screen at open-pit mines and each crusher, screen, bucket elevator, conveyor belt transfer point, thermal dryer, product packaging station, storage bin, enclosed storage area, and truck loading and unloading station at mills or concentrators commencing construction, modification or reconstruction after the date of proposal. The NSPS does not apply to facilities located in underground mines or uranium ore beneficiation processing plants.

In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 60, subpart LL.

Form numbers: None.

Respondents/affected entities: Metallic mineral processing plants.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart LL).

Estimated number of respondents: 20 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 2,330 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $268,000 (per year), which includes $13,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase of 24 labor hours due to a change in assumption. This ICR assumes all existing sources will spend time each year to re-familiarize with the regulations. There are no other changes in burden in this ICR compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years, and are not anticipated to change over the next three years; and (2) the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018–26730 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0034; FRL–9986–37–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Kraft Pulp Mills (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Kraft Pulp Mills (EPA ICR No. 1055.12, OMB Control No. 2060–0021), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2018. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 10, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0034, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov,* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for Kraft Pulp Mills apply to the following facilities at kraft pulp mills: Recovery furnaces, smelt dissolving tanks, lime kilns, digester systems, brown stock washer systems, black liquor oxidation systems, multiple effect evaporator systems and condensate stripper systems that were constructed, modified or reconstructed after the date of proposal. In pulp mills where kraft pulping is combined with neutral sulfite semi-chemical pulping, the provisions of this Subpart are applicable when any portion of the material charged to an affected facility is produced by the kraft pulping operation. Facilities may be exempt from the total reduced sulfur (TRS) standard if the facility can demonstrate that TRS emissions from a new, modified, or reconstructed brown

stock washer can be neither technically nor economically feasible to control.

In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 60, subpart BB.

Form numbers: None.

Respondents/affected entities: Kraft pulp mills.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart BB).

Estimated number of respondents: 97 (total).

Frequency of response: Initially, occasionally and semiannually.

Total estimated burden: 13,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $5,020,000 (per year), which includes $3,510,000 in annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is an adjustment decrease in the estimated burden and cost as currently identified in the OMB Inventory of Approved Burdens. The decrease is not due to any program changes. The change in burden is due to an industry decline since the last ICR renewal, resulting in a decrease in the number of respondent subject to the standard.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018–26729 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R09–OAR–2017–0473; FRL–9987–65–Region 9]

Clean Air Act Prevention of Significant Deterioration Permit Issued to Palmdale Energy LLC for the Palmdale Energy Project

AGENCY: Environmental Protection Agency.

ACTION: Notice of final action.

SUMMARY: This notice announces that the Environmental Protection Agency, Region IX (EPA Region IX) issued a final permit decision to Palmdale Energy, LLC for a Clean Air Act Prevention of Significant Deterioration (PSD) permit for the construction of the Palmdale Energy Project (PEP).

DATES: The final PSD permit decision for the PEP was issued and became effective on October 25, 2018. Pursuant to section 307(b)(1) of the Clean Air Act, judicial review of this final permit decision, to the extent it is available, may be sought by filing a petition for review in the United States Court of Appeals for the Ninth Circuit within 60 days of December 11, 2018.

ADDRESSES: The EPA established a docket for this action under Docket ID No. EPA–R09–OAR–2017–0473. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the docket index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov.* Please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information about accessing docket materials for this action.

FOR FURTHER INFORMATION CONTACT: Lisa Beckham, Permits Office (Air-3), U.S. Environmental Protection Agency, Region IX, (415) 972–3811, *beckham.lisa@epa.gov.* Anyone who wishes to review the EPA's Environmental Appeals Board (EAB) decision described below or documents in the EAB's electronic docket for its decision can obtain them at *http://www.epa.gov/eab/.* The final PSD permit is available in the electronic docket for this action at *http://www.regulations.gov* (Docket ID: EPA–R09–OAR–2017–0473).

SUPPLEMENTARY INFORMATION:

Notice of Final Action

On April 25, 2018, EPA Region IX initially issued PSD Permit No. SE 17–01 to Palmdale Energy, LLC under 40 CFR 124.15, authorizing the construction and operation of the PEP. By its own terms, and consistent with 40 CFR 124.15(b), the effective date of the permit was delayed as the result of the filing of a petition for review of the Region's permit decision with the EAB.

On October 23, 2018, the EAB denied review of the permit decision. *See In re Palmdale Energy LLC,* PSD Appeal No. 18–01 (EAB Oct. 23, 2018), 17 E.A.D. ___ (Order Denying Review). Following the EAB's action, pursuant to 40 CFR 124.19(l)(2), EPA Region IX issued a final permit decision on October 25, 2018. All conditions of the PEP PSD permit, as initially issued by EPA Region IX on April 25, 2018, were final and effective as of October 25, 2018.

Dated: November 13, 2018.

Elizabeth J. Adams,

Division Director, Region IX.

[FR Doc. 2018–26687 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0066; FRL–9986–51–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Ferroalloys Production: Ferromanganese and Silicomanganese (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Ferroalloys Production: Ferromanganese and Silicomanganese (EPA ICR No. 1831.07, OMB Control No. 2060–0391), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2018. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 10, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0066, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public

docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets*.

Abstract: The NESHAP for Ferroalloys Production: Ferromanganese and Silicomanganese applies to new and existing ferroalloy production facilities that manufacture ferromanganese and silicomanganese, and that are either major sources of hazardous air pollutant (HAP) emissions or are co-located at major sources of HAPs. The following affected facilities at ferroalloy production plants are subject to this NESHAP rule: Submerged arc furnaces; metal oxygen refining processes; crushing and screening operations; and fugitive dust sources. New facilities include those that commenced construction or reconstruction after the date of proposal.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance with 40 CFR part 63, subpart XXX.

Form numbers: None.

Respondents/affected entities: Ferroalloy production facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart XXX).

Estimated number of respondents: 2 (total).

Frequency of response: Initially, quarterly, semiannually, and annually.

Total estimated burden: 1,170 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $133,000 (per year); there are no annualized capital/startup and operation & maintenance costs.

Changes in the estimates: There is an increase in the total estimated respondent burden compared with the ICR currently-approved by OMB. The adjustment increase in burden is due to more accurate estimates of existing and anticipated new sources, as identified during the development of the final rule amendments.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018–26733 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0062; FRL–9986–60–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Pesticide Active Ingredient Production (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Pesticide Active Ingredient Production (EPA ICR No. 1807.09, OMB Control No. 2060–0370), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through December 31, 2018. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before January 10, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0062 to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed either online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets*.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pesticide Active Ingredient Production (40 CFR part 63, subpart MMM) apply to existing and new facilities engaged in the production of pesticide active ingredients (PAIs) that emit HAPs. New facilities include those that commenced construction, modification or reconstruction after the date of proposal.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining

compliance with 40 CFR part 63, subpart MMM.

Form numbers: None.

Respondents/affected entities: Owners and operators of pesticides active ingredient production operations.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart MMM).

Estimated number of respondents: 18.

Frequency of response: Initially, quarterly, and semiannually.

Total estimated burden: 12,100 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,350,000 (per year), which includes $26,500 in annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is a decrease in the total capital/startup cost and O&M cost due to a correction. This ICR corrects an error in the capital/startup cost calculation in the previous ICR, as existing sources are not expected to incur capital/startup costs associated with purchasing PRD electronic indicators. There is also a small adjustment increase in the estimated labor hours due to a change in assumption. This ICR assumes all existing sources will take some time to re-familiarize with the regulations each year.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2018–26732 Filed 12–10–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1207]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before February 11, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1207.

Title: Sections 25.701, Other DBS Public Interest Obligations, and 25.702, Other SDARS Public Interest Obligations.

Form Number: None.

Type of Review: Extension of an existing collection.

Respondents: Business or other for profit entities.

Number of Respondents and Responses: 3 respondents and 3 responses.

Estimated Hours per Response: 18 hrs.

Frequency of Response: On occasion reporting requirement, Recordkeeping requirement, Third party disclosure requirement.

Total Annual Burden: 54 hours.

Total Annual Cost: $592.

Obligation to Respond: Required to be obtained or retained for benefits. The statutory authority for this information collection is contained in sections 154, 301, 302, 303, 307, 309, 319, 332, 605, and 721 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Act Assessment: The Commission prepared a system of records notice (SORN), FCC/MB–2, ''Broadcast Station Public Inspection Files,'' that covers the PII contained in the broadcast station public inspection files located on the Commission's website. The Commission will revise appropriate privacy requirements as necessary to include any entities and information added to the online public file in this proceeding.

Needs and Uses: In 2012, the Commission replaced the decades-old requirement that commercial and noncommercial television stations maintain public files at their main studios with a requirement to post most of the documents in those files to a central, online public file hosted by the Commission. On January 28, 2016, the Commission adopted a Report and Order (''R&O'') in MB Docket No. 14–127, FCC 16–4, In the Matter of Expansion of Online Public File Obligations to Cable and Satellite TV Operators and Broadcast and Satellite Radio Licensees, expanding the requirement that public inspection files be posted to the FCC-hosted online public file database to satellite TV (also referred to as ''Direct Broadcast Satellite'' or ''DBS'') providers and to satellite radio (also referred to as ''satellite Digital Audio Radio Services'' or ''SDARS'') licensees, among other entities. The Commission stated that its goal is to make information that these entities are already required to make publicly available more accessible while also reducing costs both for the government and the public sector. The Commission took the same general approach to transitioning these entities to the online file that it took with television broadcasters in 2012, tailoring the requirements as necessary to the different services. The Commission also took similar measures to minimize the effort and cost entities must undertake to move their public files online. Specifically, the Commission required entities to upload to the online public file only documents that are not already on file with the Commission or that the Commission maintains in its own database. The Commission also exempted existing political file material from the online file requirement and required that political file documents be uploaded only on a going-forward basis.

The Commission first adopted a public inspection file requirement for broadcasters more than 40 years ago. The public file requirement grew out of Congress' 1960 amendment of Sections 309 and 311 of the Communications Act of 1934. Finding that Congress, in enacting these provisions, was guarding

''the right of the general public to be informed, not merely the rights of those who have special interests,'' the Commission adopted the public inspection file requirement to ''make information to which the public already has a right more readily available, so that the public will be encouraged to play a more active part in dialogue with broadcast licensees.'' The information provided in the public file enables citizens to engage in an informed dialog with their local video provider or to file complaints regarding provider operations. Satellite TV (also known as ''Direct Broadcast Satellite'' or ''DBS'') providers and satellite radio (also referred to as ''Satellite Digital Audio Radio Services'' or ''SDARS'') licensees have public and political file requirements modeled, in large part, on the longstanding broadcast requirements. With respect to DBS providers, the Commission adopted public and political inspection file requirements in 1998 in conjunction with the imposition of certain public interest obligations, including political broadcasting requirements, on those entities. DBS providers were required to ''abide by political file obligations similar to those requirements placed on terrestrial broadcasters and cable systems'' and were also required to maintain a public file with records relating to other DBS public interest obligations. The Commission imposed equal employment opportunity and political broadcast requirements on SDARS licensees in 1997, noting that the rationale behind imposing these requirements on broadcasters also applies to satellite radio.

The information collection requirements contained in 47 CFR 25.701(d) require each DBS provider to keep and permit public inspection of a complete and orderly record (political file) of all requests for DBS origination time made by or on behalf of candidates for public office, together with an appropriate notation showing the disposition made by the provider of such requests, and the charges made, if any, if the request is granted. The disposition includes the schedule of time purchased, when the spots actually aired, the rates charged, and the classes of time purchased. Also, when free time is provided for use by or on behalf of candidates, a record of the free time provided is to be placed in the political file. All records required to be retained by this section must be placed in the political file as soon as possible and retained for a period of two years. DBS providers must make available, by fax, email, or by mail upon telephone request, copies of documents in their political files and assist callers by answering questions about the contents of their political files. If a requester prefers access by mail, the DBS provider must pay for postage but may require individuals requesting documents to pay for photocopying. If a DBS provider places its political file on its website, it may refer the public to the website in lieu of mailing copies.

Any material required to be maintained in the political file must be made available to the public by either mailing or website access or both.

The information collection requirements contained in 47 CFR 25.701(d) require DBS providers to place all new political file material required to be retained by this section in the online file hosted by the Commission.

47 CFR 25.701(f)(6) information collection requirements require each DBS provider to maintain a public file containing a complete and orderly record of quarterly measurements of: Channel capacity and yearly average calculations on which it bases its four percent reservation, as well as its responses to any capacity changes; a record of entities to whom noncommercial capacity is being provided, the amount of capacity being provided to each entity, the conditions under which it is being provided and the rates, if any, being paid by the entity; and a record of entities that have requested capacity, disposition of those requests and reasons for the disposition. All records required by this provision must be placed in a file available to the public as soon as possible and be retained for a period of two years.

47 CFR 25.701(f)(6) to require DBS providers to place all public file material required to be retained by this section in the online file hosted by the Commission. Each DBS provider must place in the online file the records required to be placed in the public inspection file by 47 CFR 25.701(e)(commercial limits in children's programs) and by 47 CFR 25.601 and Part 76, Subpart E (equal employment opportunity requirements) and retain those records for the period required by those rules. In addition, each DBS provider is required to provide a link to the public inspection file hosted on the Commission's website from the home page of its own website, if the provider has a website, and provide on its website contact information for a representative who can assist any person with disabilities with issues related to the content of the public files. Each DBS provider is also required to include in the online public file the name, phone number, and email address of the licensee's designated contact for questions about the public file. In addition, each DBS provider must place the address of the provider's local public file in the Commission's online file unless the provider has fully transitioned to the FCC's online public file (*e.g.,* posts to the FCC's online file database all public and political file material required to be maintained in the public inspection file) and also provides online access via the provider's own website to back-up political file material in the event the online file becomes temporarily unavailable.

47 CFR 25.702(b) requires each SDARS licensee to maintain a complete and orderly record (political file) of all requests for SDARS origination time made by or on behalf of candidates for public office, together with the disposition made by the provider of such requests, and the charges made, if any, if the request is granted. The disposition must include the schedule of time purchased, when the spots actually aired, the rates charged, and the classes of time purchased. Also, when free time is provided for use by or on behalf of candidates, a record of the free time provided is to be placed in the political file. SDARS licensees are required to place all records required by this section in the political file as soon as possible and retain the record for a period of two years.

The information collection requirements contained in 47 CFR 25.702(c) require each SDARS applicant or licensee to place in the online file hosted by the Commission the records required to be placed in the public inspection file by 47 CFR 25.601 and 73.2080 (equal employment opportunities) and to retain those records for the period required by those rules. Each SDARS licensee must provide a link to the public inspection file hosted on the Commission's website from the home page of its own website, if the licensee has a website, and provide on its website contact information for a representative who can assist any person with disabilities with issues related to the content of the public files. Each SDARS licensee is also required to include in the online public file the name, phone number, and email address of the licensee's designated contact for questions about the public file. In addition, each SDARS licensee must place the address of the provider's local public file in the Commission's online file unless the provider has fully transitioned to the FCC's online public file (*i.e.,* posts to the Commission's online public file all

public and political file material required to be maintained in the public inspection file) and also provides online access via the licensee's own website to back-up political file material in the event the online file becomes temporarily unavailable.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2018–26788 Filed 12–10–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0265]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before February 11, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0265.

Title: Section 80.868, Card of Instructions.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 4,506 respondents; 4,506 responses.

Estimated Time per Response: 10 minutes (0.167 hours).

Frequency of Response: Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154, 303, 307(e), 309 and 332.

Total Annual Burden: 753 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The third party disclosure requirement contained in 47 CFR 80.868 of the Commission's rules is necessary to ensure that radiotelephone distress procedures must be securely mounted and displayed in full view of the principal operating position on board certain vessels (300 gross tons) required by the Communications Act or the International Convention for Safety of Life at Sea to be equipped with a radiotelephone station.

The information is used by a vessel radio operator during an emergency situation, and is designed to assist the radio operator to utilize proper distress procedures during a time when he or she may be subject to considerable stress or confusion.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2018–26789 Filed 12–10–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, December 13, 2018 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC (12th floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Correction and Approval of Minutes for December 6, 2018
Draft Advisory Opinion 2018–15: Wyden
Draft Advisory Opinion 2018–12: Defending Digital Campaigns, Inc.
Draft Advisory Opinion 2018–13: OsiaNetwork LLC
Draft Final Rule and Explanation and Justification for REG 2014–02 (Multistate IEs)
Draft Legislative Recommendations 2018
Fiscal Year 2020 Budget Amendment Request
2019 Meeting Dates
Election of Officers
Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Dayna C. Brown,

Secretary and Clerk of the Commission.

[FR Doc. 2018–26839 Filed 12–7–18; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, December 13, 2018 following the open meeting.

PLACE: 1050 First Street NE, Washington, DC.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

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.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Laura Sinram,

Deputy Secretary of the Commission.

[FR Doc. 2018–26842 Filed 12–7–18; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Privacy Act of 1974; System of Records

AGENCY: Federal Retirement Thrift Investment Board (FRTIB).

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, 5 U.S.C. 552a, the Federal Retirement Thrift Investment Board (FRTIB) is proposing to establish a new system of records. Records contained in this system will be used to educate participants about various aspects of the TSP.

DATES: This system will become effective upon its publication in today's **Federal Register**, with the exception of the routine uses, which are effective January 10, 2019. FRTIB invites written comments on the routine uses or other aspects of this system of records. Submit any comments by January 10, 2019.

ADDRESSES: You may submit written comments to FRTIB by any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Fax:* (202) 942–1676.
- *Mail or Hand Delivery:* Office of General Counsel, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Marla Greenberg, Chief Privacy Officer, Federal Retirement Thrift Investment Board, Office of General Counsel, 77 K Street NE, Suite 1000, Washington, DC 20002, (202) 942–1600. For access to any of the FRTIB's systems of records, contact Amanda Haas, FOIA Officer, Office of General Counsel, at the above address and phone number.

SUPPLEMENTARY INFORMATION: FRTIB is proposing to establish a new system of records entitled, ''FRTIB–20, Communications, Education, and Outreach Materials.'' The proposed system of records is necessary to assist FRTIB's Office of Communications and Education in effectively educating and communicating with Thrift Savings Plan (TSP) participants and other individuals.

Files maintained as part of FRTIB–20 include: Information about TSP participants and other individuals who receive educational messages from FRTIB or who have otherwise corresponded with FRTIB, including names, personal and business phone numbers, mailing addresses, email addresses, and social media handles; aggregated data and FRTIB analysis of participant behavior; incoming feedback and other correspondence; FRTIB's response; the FRTIB responder's name and business information; additional unsolicited personal information provided by individuals; video recordings of volunteer participants; and related materials. FRTIB is proposing to add sixteen routine uses to apply to FRTIB–20.

Megan Grumbine,

General Counsel and Senior Agency Official for Privacy.

SYSTEM NAME AND NUMBER

FRTIB–20, Communications, Education, and Outreach Materials.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are located at the Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002. Records may also be maintained at additional locations for Business Continuity purposes.

SYSTEM MANAGER:

Director, Office of Communications and Education, Federal Retirement Thrift Investment Board, 77 K Street NE, Suite 1000, Washington, DC 20002, or by phone by calling (202) 942–1600.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 8474.

PURPOSE OF THE SYSTEM:

The purpose of the system is to educate TSP participants and other individuals about the TSP; to track and analyze aggregated activity to determine the effectiveness of targeted outreach campaigns; and to solicit feedback regarding FRTIB education and outreach efforts.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

TSP participants; individuals interested in TSP updates or educational events; and individuals who wish to provide feedback on TSP outreach efforts, including targeted mailings, email campaigns, educational events, social media accounts, and focus groups.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records in this system include, but are not limited to records received, created, or compiled through FRTIB social media accounts, educational outreach efforts, educational events, requests for feedback, and other communications. The type of information in the records may include the names and contact information of the data subject, including mailing addresses, email addresses, phone numbers, and social media handles, of TSP participants or other individuals interested in the TSP; aggregated participant activity data, and FRTIB analysis of participant behavior following targeted communications from FRTIB; feedback on FRTIB communications; FRTIB's response; the name and business information of FRTIB employees; additional unsolicited personal information provided by individuals; and video or audio recordings of participants and others who voluntarily participate in FRTIB's educational campaigns or events.

RECORD SOURCE CATEGORIES:

Information in this system is obtained from TSP participant accounts; individuals who sign up to receive email or SMS/text message updates and educational materials from FRTIB; and individuals who interact with the FRTIB through various social media sites or as a result of other educational outreach efforts.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Information about covered individuals may be disclosed without consent as permitted by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(b); and:

1. Routine Use—Audit: A record from this system of records may be disclosed to an agency, organization, or individual for the purpose of performing an audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to FRTIB officers and employees.

2. Breach Mitigation and Notification: Response to Breach of FRTIB Records: A record from this system of records may

be disclosed to appropriate agencies, entities, and persons when (1) FRTIB suspects or has confirmed that there has been a breach of the system of records; (2) FRTIB has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, FRTIB (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with FRTIB's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

3. Routine Use—Response to Breach of Other Records: A record from this system of records may be disclosed to another Federal agency or Federal entity, when FRTIB determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

4. Routine Use—Congressional Inquiries: A record from this system of records may be disclosed to a Congressional office from the record of an individual in response to an inquiry from that Congressional office made at the request of the individual to whom the record pertains.

5. Routine Use—Contractors, et al.: A record from this system of records may be disclosed to contractors, grantees, experts, consultants, the agents thereof, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for FRTIB, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to FRTIB officers and employees.

6. Routine Use—Former Employees: A record from this system of records may be disclosed to a former employee of the FRTIB, in accordance with applicable regulations, for purposes of responding to an official inquiry by a federal, state, or local government entity or professional licensing authority; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the FRTIB requires information or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

7. Routine Use—Investigations, Third Parties: A record from this system of records may be disclosed to third parties during the course of a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the third party officer making the disclosure.

8. Routine Use—Investigations, Other Agencies: A record from this system of records may be disclosed to appropriate federal, state, local, tribal, or foreign government agencies or multilateral governmental organizations for the purpose of investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, license, or treaty where FRTIB determines that the information would assist in the enforcement of civil or criminal laws.

9. Routine Use—Law Enforcement Intelligence: A record from this system of records may be disclosed to a federal, state, tribal, local, or foreign government agency or organization, or international organization, lawfully engaged in collecting law enforcement intelligence information, whether civil or criminal, or charged with investigating, prosecuting, enforcing or implementing civil or criminal laws, related rules, regulations or orders, to enable these entities to carry out their law enforcement responsibilities, including the collection of law enforcement intelligence.

10. Routine Use—Law Enforcement Referrals: A record from this system of records may be disclosed to an appropriate federal, state, tribal, local, international, or foreign agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

11. Routine Use—Litigation, DOJ or Outside Counsel: A record from this system of records may be disclosed to the Department of Justice, FRTIB's outside counsel, other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when: (1) FRTIB, or (2) any employee of FRTIB in his or her official capacity, or (3) any employee of FRTIB in his or her individual capacity where DOJ or FRTIB has agreed to represent the employee, or (4) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and FRTIB determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which FRTIB collected the records.

12. Routine Use—Litigation, Opposing Counsel: A record from this system of records may be disclosed to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena.

13. Routine Use—NARA/Records Management: A record from this system of records may be disclosed to the National Archives and Records Administration (NARA) or other federal government agencies pursuant to the Federal Records Act.

14. Routine Use—Redress: A record from this system of records may be disclosed to a federal, state, tribal, local, international, or foreign government agency or entity for the purpose of consulting with that agency or entity: (1) To assist in making a determination regarding redress for an individual in connection with the operations of a FRTIB program; (2) for the purpose of verifying the identity of an individual seeking redress in connection with the operations of a FRTIB program; or (3) for the purpose of verifying the accuracy of information submitted by an individual who has requested such redress on behalf of another individual.

15. Routine Use—Security Threat: A record from this system of records may be disclosed to federal and foreign government intelligence or counterterrorism agencies when FRTIB reasonably believes there to be a threat or potential threat to national or international security for which the information may be useful in countering the threat or potential threat, when FRTIB reasonably believes such use is to assist in anti-terrorism efforts, and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure.

16. A record from this system may be shared with other Federal agencies to register and notify individuals regarding TSP-related educational events.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in paper and electronic form, including on computer databases and cloud-based services, all of which are securely stored.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name, account number, email address, phone number, social media handle, demographics, or other unique identifier of the individual about whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records are maintained in accordance with General Records Schedules 6.4 (Public Affairs Records) and 6.5 (Public Customer Service Records) issued by the National Archives and Records Administration (NARA).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

FRTIB has adopted appropriate administrative, technical, and physical controls in accordance with FRTIB's security program to protect the security, confidentiality, availability, and integrity of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records within this system must submit a request pursuant to 5 CFR part 1630. Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual, such as a Power of Attorney, in order for the representative to act on their behalf.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

See Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2018–26697 Filed 12–10–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2018–0115]

Advancing Tobacco Control Practices To Prevent Initiation of Tobacco Use Among Youth and Young Adults, Eliminate Exposure to Secondhand Smoke, and Identify and Eliminate Tobacco-Related Disparities; Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) leads comprehensive efforts to prevent the initiation of tobacco use among youth and young adults; eliminate exposure to secondhand smoke; help current smokers quit; and identify and eliminate tobacco-related disparities. In late 2017, CDC solicited input from the public in the **Federal Register** Notice 82 FR 50428 regarding nationwide priorities for cessation. CDC is currently reviewing and compiling public comments to inform future activities that could efficiently and cost effectively help people quit using tobacco by employing evidence-based treatment options. CDC will share the outcome of this request for information with the public on a date to be determined. Now, CDC is seeking information to inform future activities to advance tobacco control practices that prevent initiation of tobacco use among youth and young adults; eliminate exposure to secondhand smoke; and identify and eliminate tobacco-related disparities.

DATES: Written comments must be received on or before February 11, 2019.

ADDRESSES: Submit comments by any one of the following methods:

- *Internet:* Electronic comments may be sent via *http://www.regulations.gov,* docket control number CDC–2018–0115. Please follow the directions on the site to submit comments; or

Mail: Comments may also be sent by mail to the attention of Randi Frank, Office on Smoking and Health, Centers for Disease Control and Prevention, 4770 Buford Hwy, Mail Stop S107–7, Atlanta, GA 30341.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to, including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Randi Frank, Office on Smoking and Health, Centers for Disease Control and Prevention, 4770 Buford Hwy, Mail Stop S107–7, Atlanta, GA 30341; Telephone (770) 488–5114; Email: *OSHFRN@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Scope of Problem

Tobacco use is the leading cause of preventable disease, disability, and death in the United States.[1] The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; therefore, rapid elimination of their use will dramatically reduce this burden.[1]

Cigarette smoking alone causes more than 480,000 deaths each year, including more than 41,000 secondhand smoke related deaths, and costs the country over $300 billion annually in health care spending and lost productivity.[1 thnsp;2] Cigarette smoking is causally linked to numerous types of cancer, respiratory and cardiovascular diseases, diabetes, eye disease, complications to pregnancy and reproduction, and compromises the immune system.

Prevent Initiation of Tobacco Use Among Youth and Young Adults

Any form of tobacco product use is unsafe for youth, irrespective of whether it is smoked, smokeless, or electronic. Since brain development continues through the early to mid-20s, the use of products containing nicotine, including e-cigarettes, can be harmful to youth and young adults. Specifically, the use of these products can disrupt the growth of brain circuits that control attention, learning, and susceptibility to addiction.[3] In 2018, nearly 4.9 million United States middle and high school students currently used (≥1 day in past 30 days) at least one type of tobacco product, with e-cigarettes being the most commonly used tobacco product.[4] Flavors are a major factor contributing to the use of these products among young people; 85% of youth e-cigarette users report using flavors.[5] The use of e-cigarettes may also lead to future cigarette smoking among some youth.[6] In addition to e-cigarettes, youth also use several other types of tobacco products, and disparities in use of these products exist across population groups.[14]

Eliminate Exposure to Secondhand Smoke

The U.S. Surgeon General has concluded that there is no risk-free level of secondhand smoke exposure; even brief exposure can be harmful to health.[7 8] During 2011–2012, about 58 million nonsmokers in the United States were exposed to secondhand smoke, and exposure remains higher among children, non-Hispanic blacks, those living in poverty, and those who rent their housing.[9] Secondhand smoke exposure can cause heart disease, lung cancer, and stroke among adults, as well as the following in children: [1 7 8]

- Ear infections
- More frequent and severe asthma
- Respiratory symptoms (for example, coughing, sneezing, and shortness of breath)
- Respiratory infections (bronchitis and pneumonia)
- Sudden unexplained infant death syndrome (SUIDS)

Identify and Eliminate Tobacco-Related Disparities

Although progress has been made in reducing tobacco use in the general population, disparities persist across population groups.[1] These disparities can affect populations on the basis of certain factors, including but not limited to: [10 11]

- Age
- Disability
- Educational attainment
- Geographic location (*e.g.,* rural/urban)
- Income
- Mental health and substance abuse conditions
- Employment status
- Race/ethnicity
- Sex
- Sexual orientation and gender identity
- Veteran and military status

Addressing the social and environmental factors that influence tobacco use can advance equity in tobacco prevention and control, and reduce tobacco-related disparities among populations disproportionately impacted by tobacco use.[12] These efforts can help reduce the overall prevalence of tobacco use.[13]

Approach: CDC is seeking input to inform future activities to advance tobacco control practices to prevent initiation of tobacco use among youth and young adults; eliminate exposure to secondhand smoke; and identify and eliminate tobacco-related disparities. The information gathered will be used to inform activities that encompass technical assistance and guidance to state tobacco control programs and collaborative work with national governmental and nongovernmental partners, who share CDC's goals to prevent initiation of tobacco use among youth and young adults; eliminate exposure to secondhand smoke; and identify and eliminate tobacco-related disparities.

CDC is specifically interested in receiving information on the following issues:

(1) What innovative strategies are working in communities to prevent tobacco use among youth, especially in terms of flavored tobacco products and e-cigarettes?

(2) How can CDC best educate all community members about the harmful effects of secondhand smoke exposure?

(3) How can CDC support state and local health departments and their partners to improve community engagement with populations most at risk for tobacco use?

(4) What innovative strategies are effective in communities to decrease tobacco use in population groups that have the greatest burden of tobacco use and secondhand smoke exposure?

(5) What science, tools, or resources does the public health sector need CDC to develop in order to enhance and sustain tobacco prevention and control efforts?

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Dated: December 4, 2018.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2018–26708 Filed 12–10–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10102 and CMS–10377]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 11, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10102 National Implementation of the Hospital CAHPS Survey

CMS–10377 Student Health Insurance Coverage

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* National Implementation of the Hospital CAHPS Survey; *Use:* The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey, also known as the CAHPS® Hospital Survey or Hospital CAHPS®, is a standardized survey instrument and data collection methodology that has been in use since 2006 to measure patients' perspectives of hospital care. While many hospitals collect information on patient satisfaction, HCAHPS created a national standard for the collection and public reporting of information that enables valid comparisons to be made across all hospitals to support consumer choice.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), out of an abundance of caution, in the face of a nationwide epidemic of opioid over prescription, we finalized a refinement to the HCAHPS Survey measure as used in the Hospital Inpatient Quality Reporting Program by removing the previously adopted Pain Management questions and incorporating new Communication About Pain questions beginning with patients discharged in January 2018. As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37218), since finalization of the Communication About Pain questions, we have received feedback that some stakeholders are concerned that, although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled, the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey.

In response to stakeholder feedback, recommendations from the *President's Commission on Combatting Drug Addiction and the Opioid Crisis,* to comply with the requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115–271), and to avoid any potential unintended consequences under the Hospital Inpatient Quality Reporting (IQR) Program, CMS is revising the HCAHPS survey by removing the three recently revised pain communication questions. The removal of these questions is effective with October 2019 discharges. At that point, the HCAHPS Survey will consist of 29 questions which will decrease the burden hours. *Form Number:* CMS–10102 (OMB control number 0938–0981); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 4,200; *Total Annual Responses:* 3,104,200; *Total Annual Hours:* 379,290. (For policy questions regarding this collection contact William Lehrman at 410–786–1037.)

2. *Type of Information Collection Request:* Extension; *Title of Information Collection:* Student Health Insurance Coverage; *Use:* Under the Student

Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), student health insurance coverage is a type of individual health insurance coverage provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students who are enrolled in that institution and their dependents. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule provided that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS–10377 (OMB control number 0938–1157); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 52; *Total Annual Responses:* 1,176,235; *Total Annual Hours:* 52. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

Dated: December 6, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–26790 Filed 12–10–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4087]

The Food and Drug Administration's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock; 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 a public meeting entitled ''FDA's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock.'' Stakeholders, including healthcare providers (HCPs) and medical specialty groups, have expressed concerns regarding the availability of certain compounded drug products from outsourcing facilities that they would like to have on-hand as in-office supplies of non-patient-specific compounded drugs (''office stock''). The purpose of the public meeting is to provide HCPs, outsourcing facilities, entities considering becoming outsourcing facilities, and other interested parties with an opportunity to present to FDA their perspectives concerning access to office stock from outsourcing facilities in light of FDA's enforcement policies as proposed in the revised draft guidance on current good manufacturing practice (CGMP) for human drug compounding outsourcing facilities.

DATES: The public meeting will be held on May 21, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by June 21, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For 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 June 21, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 21, 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 Docket No. FDA–2018–N–4087 for ''FDA's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' are 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: Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–5092.

SUPPLEMENTARY INFORMATION:

I. Background

A. Drug Compounding

Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as for a patient who has an allergy to a certain dye contained in an FDA-approved drug product and needs a medication compounded without that dye, or an elderly patient or a child who cannot swallow a pill and needs a medicine in a liquid form that is not available in an approved product. Drug products can be compounded consistent with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) by licensed pharmacists in State-licensed pharmacies and Federal facilities, or by licensed physicians, or consistent with section 503B of the FD&C Act (21 U.S.C. 353b) by compounders known as outsourcing facilities.

Sometimes, it is necessary for HCPs in hospitals, clinics, offices, or other settings to have a certain compounded drug product on hand, so they can administer it to a patient who presents with an immediate need for the compounded drug product. Such drug products are often known as ''office stock,'' and outsourcing facilities are uniquely permitted to supply these compounded products in accordance with the law.

For example, if a patient presents at an ophthalmologist's office with a fungal eye infection, timely administration of a compounded antifungal medication may be critical to preventing vision loss. In such a case, the ophthalmologist may need to inject the patient with a compounded drug product immediately, rather than writing a prescription and waiting for the drug product to be compounded and shipped to the prescriber. In other cases, compounded drug products may need to be administered by a healthcare practitioner in his or her office because it would not be safe for the patient to take the drug home for self-administration, and it would be preferable for the physician to have the drug in his or her office to administer immediately upon diagnosis, rather than asking the physician to order the drug and have the patient return to the healthcare practitioner for administration.

Although compounded drugs can serve an important role for certain patients in cases such as these, they also can pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. Because compounded drug products are subject to a lower regulatory standard than FDA-approved drug products, they present a greater risk to patients and should not be administered to patients unless their medical needs cannot be met by FDA-approved drug products.

B. Compounding Under the FD&C Act

Sections 503A and 503B of the FD&C Act address human drug compounding. Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning CGMP requirements);
- section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. Among other conditions, to qualify for the exemptions under section 503A, the drug product must be compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

New section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities.* Section 503B defines *outsourcing facility,* in part, as a facility that is engaged in the compounding of sterile drugs (section 503B(d)(4)(A)(i)). An outsourcing facility may engage in nonsterile compounding provided that it also engages in the compounding of sterile drugs, and provided that it compounds all of its drugs (both sterile and nonsterile) in accordance with the conditions of section 503B.

Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- Section 502(f)(1);
- section 505; and
- section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).

In contrast to compounders compounding in accordance with section 503A of the FD&C Act, outsourcing facilities may, but need not, obtain prescriptions for identified individual patients for their

compounded drug products (section 503B(d)(4)(C)). Outsourcing facilities are subject to CGMP requirements in section 501(a)(2)(B). They must also be inspected by FDA according to a risk-based schedule and are subject to specific adverse event reporting requirements and other conditions that help to mitigate the risks of the drug products they compound.

C. CGMP Requirements for Outsourcing Facilities

Elsewhere in this issue of the **Federal Register**, FDA announced the availability of a revised draft guidance for industry entitled ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' (revised draft guidance). FDA previously issued a draft guidance for industry on this subject in July 2014 (79 FR 37743). This guidance, once final, will provide for conditions under which FDA generally does not intend to take regulatory action against an outsourcing facility regarding certain CGMP requirements in 21 CFR parts 210 and 211 during the interim period before FDA issues regulations specific to outsourcing facilities. In developing policies pertaining to CGMP requirements for outsourcing facilities, FDA seeks to recognize the differences between outsourcing facilities and conventional drug manufacturers and to develop policies that reflect the specific compounding operations conducted by outsourcing facilities. The revised draft guidance proposes a risk-based approach to enforcement of CGMP requirements, tailored to the size and scope of outsourcing facilities' operations. The policies are aimed at making it more feasible for entities to register as outsourcing facilities to compound drugs for office stock in accordance with CGMP requirements, while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard drug products.

In the revised draft guidance, FDA made a number of revisions to address comments submitted on the 2014 draft. For example, the revised draft guidance differentiates between CGMP requirements applicable to sterile drug products and nonsterile drug products where appropriate. Among other changes, FDA made revisions to address comments on (1) stability testing, including the assignment of a beyond use date (BUD) as an expiration date; (2) a clear definition of ''in-use time,'' distinguishing it from ''BUD'' and ''expiration date''; (3) testing batches before release for distribution; and (4) collection and use of samples retained from distributed batches, known as reserve samples. For a more comprehensive discussion of the policies proposed in the revised draft guidance, please see the revised draft guidance (available at: *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*) and associated notice of availability, which FDA is publishing elsewhere in this issue of the **Federal Register**. In the docket for the revised draft guidance, FDA is seeking comment on whether the conditions outlined appropriately balance the risks and needs associated with compounded drugs produced for office stock.

II. Topics for Discussion at the Public Meeting

FDA is seeking public input regarding outsourcing facilities supplying compounded drugs for office stock in light of the CGMP policies described in the revised draft guidance, if finalized as written. FDA has developed a list of topics to facilitate a productive discussion at the public meeting. This list is not intended to be exhaustive, and FDA encourages comments on the potential implications of the policies pertaining to compliance with CGMP requirements described in the revised draft CGMP guidance, if finalized as written, for outsourcing facilities supplying drugs compounded for office stock. Policies include, but are not limited to, those related to stability studies, beyond use dating, and release testing. Issues that are of specific interest to the Agency include the following:

- Perspectives related to demand and supply of office stock, including:
  - Ways in which HCPs seek to identify outsourcing facilities that compound the drugs they want for office stock, as well as issues, if any, with this process.
  - Communications between HCPs and outsourcing facilities to address potential issues related to requested formulations, timing, and order size.
  - Coordination or consolidation of orders among providers for same or similar compounded drug products.
  - HCPs' experiences with the availability of office stock products from outsourcing facilities.
- Perspectives related to orders for drug products that an outsourcing facility has not made or does not routinely make.
  - Factors outsourcing facilities consider before deciding whether to fill an order for a requested compounded drug product that it has not previously made or does not routinely make.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities filling orders for requested products not previously or routinely made.
- Perspectives related to small volume orders of office stock products, including:
  - HCPs' experiences seeking small volume orders from outsourcing facilities.
  - Factors outsourcing facilities consider before determining whether to produce small batches of compounded drug products for office stock.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities' decisions regarding filling small volume orders and/or producing small batches of compounded drug products for office stock.
  - Whether/how the revisions proposed in the revised draft guidance would affect registration of compounders engaged in smaller-scale production as outsourcing facilities.
- Perspectives related to beyond use dating for office stock products, including:
  - How long HCPs seek to keep office stock drug products before use.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities' production of compounded drug products for office stock with beyond use dating desired by HCPs.

FDA will post the agenda and other meeting materials at least 5 days before the meeting on the public meeting website. More information regarding the meeting, including the public meeting website address, will be posted at: *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by May 7, 2019. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. More information regarding the meeting, including the public meeting website address and registration instructions, will be posted at: *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.*

Registration is free and in-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each

organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8:30 a.m. We will post information at *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact *CompoundingPublicMeeting@fda.hhs.gov* no later than May 14, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. All requests to make oral presentations must be received by March 1, 2019. You will also be asked to send *CompoundingPublicMeeting@fda.hhs.gov* a brief summary your comments by March 1, 2019. 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. For more information on oral presentation requests, visit *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.* 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. We will do our best to accommodate all stakeholders who wish to speak; however, the duration of comments may be limited by time constraints, including time allowances for each topic. Presenters will be notified of their selection no later than May 7, 2019. If selected for presentation, any presentation materials must be emailed to the *CompoundingPublicMeeting@fda.hhs.gov* no later than May 14, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Further information regarding the webcast, including the address for the webcast, will be made available at least 2 days in advance of the meeting on the public meeting website. More information regarding the meeting, including the public meeting website address, will be posted at: *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.* 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.

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26725 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0779]

Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a revised draft guidance entitled ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' This revised draft guidance describes FDA's policies regarding compounders registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as outsourcing facilities and the current good manufacturing practice (CGMP) requirements in FDA regulations. Based on feedback from stakeholders and comments received on the initial draft guidance, the guidance is being revised, in part, to reflect further consideration of how CGMP requirements should be applied in light of the size and scope of an outsourcing facility's operations.

DATES: Submit either electronic or written comments on the revised draft guidance by February 11, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments concerning the collection of information under the Paperwork Reduction Act of 1995 (PRA) proposed in the revised draft guidance by February 11, 2019.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–0779 for ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' 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 under the PRA to the Office of Management and Budget (OMB) 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 *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.''

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2258, Silver Spring, MD 20993–0002, 301–796–0600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' Under section 503B(b) of the FD&C Act (21 U.S.C. 353b(b)), a compounder can register as an outsourcing facility with FDA. Drug products compounded in an outsourcing facility can qualify for exemptions from FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and the drug supply chain security requirements in section 582 of the FD&C Act (21 U.S.C. 360eee–1), if the requirements in section 503B are met. Outsourcing facilities are inspected by FDA according to a risk-based schedule and must comply with other provisions of the FD&C Act, including CGMP requirements under section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)). FDA intends to issue CGMP regulations specific to outsourcing facilities. Until final regulations are issued, this draft guidance describes FDA's policies regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211.

This draft guidance revises the draft guidance for industry entitled ''Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act,'' which published in July 2014 (79 FR 37743). This revised draft guidance applies to drugs compounded in accordance with section 503B. In addition, this guidance generally applies to drugs that outsourcing facilities repackage and biological products that outsourcing facilities mix, dilute, or repackage in accordance with relevant guidance for outsourcing facilities. This revised draft guidance reflects FDA's intent to recognize the differences between outsourcing facilities and conventional drug manufacturers and to tailor CGMP requirements to the nature of the specific compounding operations conducted by outsourcing facilities while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard drug products.

The comment period on the initial draft guidance ended on September 2, 2014. FDA received 26 comments on the draft guidance. In response to received comments or on its own initiative, FDA made changes and updates in the revised draft guidance as follows.

FDA received a number of comments regarding the requirements in FDA regulations applicable to nonsterile drug products because the draft guidance focused primarily on sterile compounding. To address these comments, the revised draft guidance differentiates between requirements applicable to sterile drug products and nonsterile drug products where appropriate. The revised draft guidance also distinguishes the risks presented by using sterile and nonsterile components in producing sterile drug products and offers recommendations and policies on quality control commensurate with the risk. Further, the revised draft guidance addresses concerns raised regarding FDA's policies in several other areas. FDA made significant revisions to address comments on (1) stability testing, including the assignment of a beyond use date (BUD) as an expiration date; (2) release testing; (3) the potential use of a drug master file to address contract laboratory testing arrangements and testing of component quality before use in compounding; (4) the use of accredited third-party laboratories to perform testing; (5) a clear definition of ''in-use time,'' distinguishing it from ''BUD'' and ''expiration date''; and (6) reserve samples.

We note that the default BUDs and storage conditions associated with nonsterile drug products described in this revised draft guidance differ from those described for nonsterile repackaged drug products in FDA's guidance for industry entitled ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities'' (Repackaging guidance). FDA believes that the BUDs described in this revised draft CGMP guidance are also relevant to nonsterile drug products repackaged by outsourcing facilities. When this guidance is finalized, we intend to make conforming revisions to the BUDs for repackaged nonsterile drug products in the Repackaging guidance, as appropriate.

Finally, this revised draft contains revisions to the conditions under which the Agency generally would not intend to take regulatory action regarding the requirement to test the finished product before release (see § 211.165 (21 CFR 211.165)). These revisions make a broader range of production volumes eligible for the relevant enforcement policy, which we believe would encourage additional compounders to register as outsourcing facilities. Compared to compounders that are not registered under section 503B of the

FD&C Act, outsourcing facilities are subject to increased Federal oversight through FDA inspection on a risk-based schedule, as well as to additional standards that help to assure the quality of their compounded drug products. Outsourcing facilities produce drug products for hospitals, clinics, or healthcare practitioners to keep on hand as ''office stock'' for patients who present with an immediate need for them. The revised draft guidance addresses standards critical to reducing the risk of patient harm while balancing appropriate flexibility. FDA is seeking public comment on whether the conditions outlined in the revised draft appropriately balance the risks and needs associated with drugs produced for office stock, including comments on the production volumes specified in the guidance.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from OMB for each collection of information that 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** for 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 collection of information associated with this document, FDA invites comments on these topics: (1) Whether the proposed information collected 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 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.

1. Quality Assurance Activities

A quality control unit must be established by outsourcing facilities to oversee various aspects of drug production and to monitor quality assurance (see, *e.g.,* § 211.22 (21 CFR 211.22)). The responsibilities of the quality control unit must be established in procedures (§ 211.22(d)) and should include investigations and development and oversight of appropriate corrective and preventive actions regarding results of tests and examinations, unexpected results or trends, failures that occur during validation or revalidation of sterilization or depyrogenation processes, stability failures, environmental and personnel monitoring results that exceed alert or action limits, process deviations or equipment malfunctions that involve critical equipment, and complaints that indicate possible drug product contamination or other risks to patients. The quality control unit must periodically (at least annually) review records of compounding operations to evaluate the quality standards for each drug product to determine the need for changes in specifications or control procedures (21 CFR 211.180(e)).

FDA estimates that annually approximately 74 outsourcing facilities [1] (''No. of Recordkeepers'' in table 1, row 1) will individually establish approximately 13 procedures on the responsibilities of the quality control unit (''No. of Records per Recordkeeper'' in table 1, row 1) as described in section III.A of the guidance. FDA also estimates that preparing and maintaining these procedures will take approximately 3 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 1).

2. Facility Design

The revised draft guidance describes those elements of facility design of outsourcing facilities that are considered critical to assuring the quality of sterile drug products at those facilities. For example, the draft guidance states that sterile drugs should be produced only in ISO 5 (International Organization for Standardization) or better air quality and that the ISO 5 zone or critical area must be qualified (*i.e.,* shown to meet the specifications) (see §§ 211.42 and 211.113(b) (21 CFR 211.42 and 211.113(b))). The revised draft guidance lists certain studies and tests that should be successfully performed for outsourcing facilities and states that the results of these studies and tests should be documented.

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 2) will individually document approximately 20 studies and tests (''No. of Records per Recordkeeper'' in table 1, row 2) that are critical to assuring the quality of sterile drug products. FDA also estimates that preparing and maintaining each record as described in the guidance will take on average approximately 1.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 2).

3. Control Systems and Procedures for Maintaining Suitable Facilities

The revised draft guidance describes procedures that should be established and followed that assign responsibility for sanitation and describe the cleaning schedules, methods, equipment, and materials to be used in cleaning buildings and facilities. For multiuse facilities and nondedicated equipment, changeover and cleaning procedures for equipment and utensils must be established and followed to prevent contamination (see §§ 211.42 and 211.67). Procedures for cleaning and disinfecting must also be established (see §§ 211.42, 211.56, and 211.67). If powder drugs are handled, procedures must be established and followed to appropriately manage cross-contamination risk (§ 211.100 (21 CFR 211.100)). Processes and procedures should minimize contamination risks posed by the number and complexity of manipulations, number of simultaneous operations and workstations, and staging of materials used in the process. Temperature and humidity must be maintained in cleanrooms; such controls are critical to reduce microbial growth (see 21 CFR 211.46). In addition, the guidance describes that procedures should ensure recording of instances when there is a loss of positive pressure in the cleanroom during production.

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 3) will individually establish and maintain approximately 6 records (procedures and documentation) for

[1] This figure is based on the number of outsourcing facilities that were registered on July 27, 2018.

maintaining suitable outsourcing facilities (''No. of Records per Recordkeeper'' in table 1, row 3). FDA also estimates that preparing and maintaining each record as described in the guidance will take on average approximately 5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 3).

4. Environmental and Personnel Monitoring

The revised draft guidance states that operations and appropriate written procedures designed to prevent microbial contamination include a well-defined and documented program for environmental monitoring that evaluates the potential routes of microbial contamination of the human drug that could arise from the air, surfaces, process, operation, and personnel practices (see §§ 211.42(c)(10)(iv), 211.100, and 211.113(b)). Personnel monitoring should include a routine program for daily/shift monitoring of operators' gloves and an appropriate schedule for monitoring other critical sites of the gown (*e.g.,* gown sleeves for hood work) during or immediately after completion of aseptic operations; establish and justify limits that are based on the criticality of the operation relative to the contamination risk to the product; and call for an investigation of results that exceed the established levels or demonstrate an adverse trend, a determination of the impact on the sterility assurance of finished products intended to be sterile, and the development and execution of appropriate corrective actions. This monitoring should take place before planned disinfection so that actual operating conditions are being assessed. In addition, an outsourcing facility or its contract laboratory should establish procedures for establishing the validity of media if microbiological media used in performing tests, including environmental and personnel monitoring, are not purchased from a qualified supplier.

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 4) will individually establish approximately 1,200 environmental and personnel monitoring procedures and records to document test results (''No. of Records per Recordkeeper'' in table 1, row 4) for aseptic processing areas. FDA also estimates that preparing and maintaining the environmental and personnel monitoring procedures as described in the guidance will take on average approximately 0.25 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 4).

5. Containers and Closures

Scientifically sound and appropriate criteria for containers and closures must be established to ensure that containers and closures used for drug products are suitable for each drug product for which they will be used (see § 211.160(b) (21 CFR 211.160(b))). Appropriate procedures must be established for testing the containers and closures to determine whether they meet the criteria for use, and the tests and results must be documented (see 21 CFR 211.84(d)(3) and 211.184). Procedures for storage, if appropriate, of sterilized containers or closures must be established in a manner to prevent contamination and to maintain sterility (see 21 CFR 211.80(a) and (b)).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 5) will individually establish and maintain approximately 300 procedures and pieces of documentation for testing containers and closures (''No. of Records per Recordkeeper'' in table 1, row 5) in the aseptic processing areas. FDA also estimates that preparing and maintaining these procedures and documentation as described in the guidance will take on average approximately 0.25 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 5).

6. Equipment

Procedures should be established and records maintained for routine calibration and maintenance of equipment (mechanical, electronic, or automated).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 6) will individually establish and maintain approximately 150 procedures and pieces of documentation for the calibration and maintenance of equipment (''No. of Records per Recordkeeper'' in table 1, row 6). FDA also estimates that preparing and maintaining these records will take on average approximately 0.25 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 6).

7. Components

Procedures should be established and records maintained concerning the source and quality of components such as raw materials or ingredients used in producing nonsterile and sterile drug products at outsourcing facilities. The revised draft guidance also states that FDA generally does not intend to take regulatory action against an outsourcing facility regarding testing components if an adequate supplier quality agreement is in place and maintained appropriately.

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 7) will individually establish and maintain approximately 150 records of testing to ensure the quality of components used in producing drug products, as recommended in the guidance (''No. of Records per Recordkeeper'' in table 1, row 7). FDA also estimates that preparing and maintaining these records will take on average approximately 4 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 7).

8. Production and Process Controls

Production and process documentation and procedures, such as batch records, must be established to assure the quality of drug products at outsourcing facilities (see § 211.100). Training on aseptic technique, cleanroom behavior, gowning, and procedures covering aseptic manufacturing area operations must be established (see 21 CFR 211.25(a)). The validation of sterilization operations (*e.g.,* holding vessels, filling equipment, lyophilizers) and periodic verification activities and results must be documented (see § 211.113(b)).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 8) will individually establish and maintain approximately 1,325 records pertaining to production and process controls, such as validation procedures and training, to ensure the quality of sterile drug products (''No. of Records per Recordkeeper'' in table 1, row 8). FDA also estimates that preparing and maintaining these records, as described in the guidance, will take on average approximately 0.25 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 8).

9. Release Testing

Drug products produced at outsourcing facilities must be tested to determine whether they meet final product specifications before release for distribution, and procedures for final release testing must be established and followed (§§ 211.165 and 211.167).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 9) will individually establish and maintain approximately 1,725 records pertaining to final release testing of drug products, including release testing

procedures and documentation (''No. of Records per Recordkeeper'' in table 1, row 9). FDA also estimates that preparing and maintaining these records, as described in the guidance, will take on average approximately 1.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 9).

If sterility testing is not completed before release under certain conditions described in Appendix A of the guidance, procedures should be established that specify that if the product fails to meet a criterion for sterility, all healthcare and other facilities that received the product should be immediately notified of the test results and provided with any appropriate information and recommendations to aid in the treatment of patients; the notification should be documented; and FDA should be notified in writing.

FDA estimates that annually approximately 10 outsourcing facilities (''No. of Respondents'' in table 2, row 1) will individually send approximately 1 notification of test results to all healthcare and other facilities that received the drug product and provide them with any appropriate information and recommendations to aid in the treatment of patients (No. of Disclosures per Respondent'' in table 2, row 1). FDA also estimates that preparing and sending each notification will take approximately 5 hours (''Average Burden per Disclosure'' in table 2, row 1).

FDA also estimates that annually approximately 10 outsourcing facilities (''No. of Respondents'' in table 3) will individually submit to FDA 1 notification of the test results for any drug product that fails to meet a sterility criterion (''No. of Responses per Respondent'' in table 3). Preparing and submitting this information will take approximately 5 hours per notification (''Average Burden per Response'' in table 3).

10. Laboratory Controls

Each laboratory used to conduct testing of components, in-process materials, and finished drug products for outsourcing facilities must follow written procedures for the conduct of each test and must document the results; establish sampling and testing procedures to ensure that components, in-process materials, and drug products conform to the product specifications; keep complete records of all tests performed to ensure compliance with established specifications and standards, including examinations and assays; and, if using a validated or an established compendial test, verify and document that the test procedure works under the conditions of actual use (see §§ 211.160 and 211.194).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 10) will individually establish and maintain approximately 200 laboratory records as described in the guidance (''No. of Records per Recordkeeper'' in table 1, row 10). FDA also estimates that preparing and maintaining these records will take on average approximately 0.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 10).

11. Stability/Expiration Dating

Stability testing is used to ensure that a drug product will retain its quality (*e.g.,* strength) and remain sterile, if applicable, through the labeled expiration date. The draft guidance states that procedures established by outsourcing facilities for assessing the stability of drug products must include the following: Using stability-indicating test methods that are reliable, meaningful, and specific; evaluating samples of the drug product in the same container-closure system in which the drug product will be marketed; evaluating samples for stability that are representative of the lot or batch from which they were obtained and are stored under suitable conditions; and testing to evaluate antimicrobial effectiveness for drug products labeled or intended to be multiple dose (see §§ 211.122, 211.160, and 211.166). The guidance states that regardless of whether an expiration date or BUD to be used as an expiration date is used, container-closure integrity testing and antimicrobial effectiveness testing (for products labeled as multiple dose) are required to be completed before a batch is released (see §§ 211.166 and 211.167). Each of these studies only needs to be conducted once for each formulation and container-closure system, and a bracketing or matrixing approach can be considered to minimize the amount of testing needed. Outsourcing facilities are also responsible for including appropriate labeled directions for use for drug products, which may include in-use time if the product requires additional manipulation before administration. Appropriate studies, including stability studies, would need to support the stated in-use time.

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 11) will individually establish and maintain approximately 75 procedures for stability studies to determine an expiration date (''No. of Records per Recordkeeper'' in table 1, row 11) for drug products. FDA also estimates that preparing and maintaining these procedures as described in the guidance will take approximately 5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 11).

FDA also estimates that annually approximately 74 outsourcing facilities (''No. of Respondents'' in table 2, row 2) will add approximately 540 expiration dates to the labeling of drug products (''No. of Disclosures per Respondent'' in table 2, row 2). FDA also estimates that preparing the labeling will take approximately 0.25 hours (''Average Burden per Disclosure'' in table 2, row 2).

12. Packaging and Labels

Packaging of drugs must ensure the sterility, if applicable, and integrity of the product until it is administered to a patient, product labels must contain required information, and labeling operations must include controls to prevent mixups (see §§ 211.94, 211.122, 211.125, 211.130, and 211.134). The following must be implemented by outsourcing facilities for packaging and labeling operations to ensure the quality of drug products: The container, closure, and packaging systems adequately protect against foreseeable external factors in storage, shipment, and use that can cause contamination or deterioration; packaging records include specimens or copies of all labels used; adequate controls are established for issuing labels, examining issued labels, and reconciling used labels to prevent mixups; different labeling and packaging operations are adequately separated to prevent mixups; and controls are established that ensure proper identification of any filled containers of products that are stored unlabeled for any period of time (see §§ 211.94, 211.122, 211.125, 211.130, 211.134, and 211.188).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 12) will individually establish and maintain approximately 20 procedures for packaging and labeling operations (''Records per Recordkeeper'' in table 1, row 12) for drug products. FDA also estimates that preparing and maintaining these procedures as described in the guidance will take approximately 5.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 12).

13. Reserve Samples

An appropriately identified reserve sample that is representative of each lot or batch of drug product must be retained and stored under conditions

consistent with product labeling (21 CFR 211.170).

FDA estimates that annually approximately 74 outsourcing facilities (''No. of Recordkeepers'' in table 1, row 13) will individually establish and maintain approximately 12 procedures and records for reserve samples (''Records per Recordkeeper'' in table 1, row 13) for drug products. FDA also estimates that preparing and maintaining these procedures and records as described in the guidance will take approximately 0.5 hours for each record (''Average Burden per Recordkeeping'' in table 1, row 13).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality assurance activities	74	13	962	3	2,886
Facility design	74	20	1,480	1.5	2,220
Control systems and procedures for maintaining suitable facilities.	74	6	444	5	2,220
Environmental and personnel monitoring	74	1,200	88,800	0.25 (15 minutes)	22,200
Containers and closures	74	300	22,200	0.25 (15 minutes)	5,550
Equipment	74	150	11,100	0.25 (15 minutes)	2,775
Components	74	150	11,100	4	44,400
Production and process controls	74	1,325	98,050	0.25 (15 minutes)	24,513
Release testing	74	1,725	127,650	1.5	191,475
Laboratory controls	74	200	14,800	0.5 (30 minutes)	7,400
Stability/Expiration dating	74	75	5,550	5	27,750
Packaging and labels	74	20	1,480	5.5	8,140
Reserve samples	74	12	888	0.5 (30 minutes)	444
Total					341,973

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of disclosure	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification that a drug product fails to meet a sterility criterion.	10	1	10	5	50
An expiration date is added to the drug product's label.	74	540	39,960	0.25 (15 minutes)	9,990
Total					10,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification to FDA that a drug product fails to meet a sterility criterion	10	1	10	5	50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26724 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1990]

Su-Chiao Kuo: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. Su-Chiao Kuo for a period of 3 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Kuo was convicted of a misdemeanor under the FD&C Act for causing the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded. In addition, FDA has determined that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. Dr. Kuo was given notice of the proposed

debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Kuo failed to request a hearing. Dr. Kuo's failure to request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable December 11, 2018.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On January 14, 2014, in the United States District Court for the Northern District of Ohio, judgment was entered against Dr. Kuo after she entered a plea of guilty to one count of misbranding, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which is a misdemeanor offense under section 303(a)(1) of the FD&C Act (21 U.S.C. 333(a)(1)).

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for this conviction is as follows: Between June 22, 2005, and November 18, 2008, Dr. Kuo was a physician (oncologist) in Ohio. During this time, Dr. Kuo purchased and received oncology drugs, including TAXOTERE (docetaxel) and ZOMETA (zoledronic acid), from a drug distributor located in Canada. These new drugs originated outside the United States and were not approved by FDA for introduction or delivery for introduction into interstate commerce in the United States. Thus, Dr. Kuo caused the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded for lacking adequate directions for use in their labeling.

As a result of this conviction, on July 13, 2018, FDA sent Dr. Kuo a notice by certified mail proposing to debar her for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding under section 306(b)(2)(B)(i)(I) of the FD&C Act that Dr. Kuo was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

The proposal offered Dr. Kuo an opportunity to request a hearing, provided her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Kuo received the proposal on July 23, 2018. Dr. Kuo did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and has waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Dr. Su-Chiao Kuo has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing findings and in consideration of the factors described in section 306(c)(3) of the FD&C Act, Dr. Su-Chiao Kuo is debarred for 3 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 306(c)(1)(B), (c)(3), and 201(dd) (21 U.S.C. 321(dd)) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Kuo in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Dr. Kuo provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Kuo during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Kuo for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2018–N–1990 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26778 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1994]

David J. Fishman: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Dr. David J. Fishman for a period of 3 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Fishman was convicted of a misdemeanor under the FD&C Act for causing the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded. In addition, FDA has determined that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. Dr. Fishman was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Fishman failed to request a hearing. Dr. Fishman's failure to

request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is applicable December 11, 2018.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On November 19, 2013, in the United States District Court for the Northern District of Ohio, judgment was entered against Dr. Fishman after he entered a plea of guilty to one count of misbranding, in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)), which is a misdemeanor offense under section 303(a)(1) of the FD&C Act (21 U.S.C. 333(a)(1)).

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for this conviction is as follows: Between January 10, 2006, and March 12, 2009, Dr. Fishman was a physician (oncologist) in Ohio. During this time, Dr. Fishman purchased and received oncology drugs, including TAXOTERE (docetaxel) and NOVANTRONE (mitoxantrone), from a drug distributor located in Canada. These new drugs originated outside the United States and were not approved by FDA for introduction or delivery for introduction into interstate commerce in the United States. Thus, Dr. Fishman caused the introduction or delivery for introduction into interstate commerce of prescription drugs that were misbranded for lacking adequate directions for use in their labeling.

As a result of this conviction, on July 27, 2018, FDA sent Dr. Fishman a notice by certified mail proposing to debar him for 3 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding under section 306(b)(2)(B)(i)(I) of the FD&C Act that Dr. Fishman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

The proposal offered Dr. Fishman an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Fishman received the proposal on August 2, 2018. Dr. Fishman did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Dr. David J. Fishman has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing findings and in consideration of the factors described in section 306(c)(3) of the FD&C Act, Dr. David J. Fishman is debarred for 3 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 306(c)(1)(B), (c)(3), and 201(dd) (21 U.S.C. 321(dd)) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Fishman in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Dr. Fishman provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Fishman during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Fishman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2018–N–1994 and sent to the Dockets Management Staff (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26722 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4162]

The Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on February 6, 2019, from 8:30 a.m. to 5 p.m. and on February 7, 2019 from 8 a.m. to 1 p.m.

ADDRESSES: FDA White Oak Conference Center, Bldg. 31, Rm. 1503 (the Great Room), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *TPSAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On February 6–7, 2019, the Committee will convene for two sessions. The first session will convene on February 6, 2019, during which the Committee will discuss an amendment to the modified risk tobacco product applications (MRTPAs), submitted by Swedish Match North America for the following snus smokeless tobacco products:

- MR0000020: General Loose;
- MR0000021: General Dry Mint Portion Original Mini;
- MR0000022: General Portion Original Large;
- MR0000024: General Classic Blend Portion White Large-12ct;
- MR0000025: General Mint Portion White Large;
- MR0000027: General Nordic Mint Portion White Large-12ct;
- MR0000028: General Portion White Large; and
- MR0000029: General Wintergreen Portion White Large.

The second session will convene, after the first session has concluded, on February 6, 2019, and continue on February 7, 2019. During the second session the Committee will discuss the MRTPA, submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC for the following smokeless tobacco product:

- MR0000108: Copenhagen Snuff Fine Cut.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before January 22, 2019. Oral presentations from the public for the first session will be scheduled between approximately 10 a.m. and 10:30 a.m. on February 6, 2019, and for the second session between approximately 8 a.m. and 8:30 a.m. on February 7, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement describing the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and the session during which they would like to speak, on or before January 14, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 15, 2019.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Caryn Cohen (see: **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26721 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on October 1, 2018, through October 31, 2018. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: November 30, 2018.

George Sigounas,

Administrator.

List of Petitions Filed

Diane Tobin, New London, Connecticut, Court of Federal Claims No: 18–1516V
2. John Homan, Peoria, Illinois, Court of Federal Claims No: 18–1517V
3. Sharon Borris, Tiffin, Ohio, Court of Federal Claims No: 18–1518V
4. Edward Boni, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1519V
5. Erin M. Kinney, Linwood, New Jersey, Court of Federal Claims No: 18–1522V
6. Michael J. Periard, Ithaca, New York, Court of Federal Claims No: 18–1524V
7. Anne M. Alexander on behalf of Marilyn Osborne Rock, Deceased, Denver, Colorado, Court of Federal Claims No: 18–1525V
8. Thomas Bade, Pearl River, New York, Court of Federal Claims No: 18–1526V
9. Deana Knowles, Middle Granville, New York, Court of Federal Claims No: 18–1527V
10. Dionni De La Cruz, Houston, Texas, Court of Federal Claims No: 18–1528V
11. Anthony Sanders, Alexandria, Louisiana, Court of Federal Claims No: 18–1529V
12. Janice Y. Atencio, Espanola, New Mexico, Court of Federal Claims No: 18–1530V
13. Dawna Michelle Cox on behalf of David Carroll Cox, Deceased, Shelbyville, Kentucky, Court of Federal Claims No: 18–1531V
14. William C. Carter, Prospect Hill, North Carolina, Court of Federal Claims No: 18–1532V
15. Sarah Huff, St. Petersburg, Florida, Court of Federal Claims No: 18–1533V
16. Jamie Blaylock, Overland Park, Kansas, Court of Federal Claims No: 18–1534V
17. Kenneth A. Bradley, Naples, Maine, Court of Federal Claims No: 18–1535V
18. Joan Benz, Maryland Heights, Missouri, Court of Federal Claims No: 18–1536V
19. Kristen Iniguez on behalf of K. J. I., San Diego, California, Court of Federal Claims No: 18–1537V
20. Durenda Whitehead and Keynard Shawtell Johnson, Sr. on behalf of K. S. J. Jr., Macon, Georgia, Court of Federal Claims No: 18–1538V
21. LaDonna Foster, Willow Brook, Illinois, Court of Federal Claims No: 18–1540V
22. Annie Brown, White Plains, New York, Court of Federal Claims No: 18–1542V
23. Heather Massey, Salt Lake City, Utah, Court of Federal Claims No: 18–1543V
24. Rebeca A. Nolan, Saugerties, New York, Court of Federal Claims No: 18–1544V
25. Randy L. Taylor, Longview, Texas, Court of Federal Claims No: 18–1545V
26. Dorn Dyttmer, Gwinn, Michigan, Court of Federal Claims No: 18–1546V
27. Paulette Falbo, Northport, New York, Court of Federal Claims No: 18–1547V
28. Robert Fulling, Chicago, Illinois, Court of Federal Claims No: 18–1549V
29. Elizabeth Valdez, San Mateo, California, Court of Federal Claims No: 18–1550V
30. Lori A. Hughes, Madison, Wisconsin, Court of Federal Claims No: 18–1554V
31. Jennifer Schlata, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1557V
32. Natalia A. Augustine, Westmont, Illinois, Court of Federal Claims No: 18–1558V
33. Kathy Cummings Gillim, Farmington Hills, Michigan, Court of Federal Claims No: 18–1560V
34. Linda Wirtshafter, Woodmere, Ohio, Court of Federal Claims No: 18–1562V
35. Thomas A. Metzger, Newport, Washington, Court of Federal Claims No: 18–1565V
36. Pamela A. Stricker and Jerry Stricker on behalf of Pamela Stricker, Lima, Ohio, Court of Federal Claims No: 18–1569V
37. Kathleen Bartholomew, Park Forest, Illinois, Court of Federal Claims No: 18–1570V
38. Michael Lusk, Granite Bay, California, Court of Federal Claims No: 18–1571V
39. Lee Meagher, Danvers, Massachusetts, Court of Federal Claims No: 18–1572V
40. Debbie Buck, Murray, Utah, Court of Federal Claims No: 18–1573V
41. Georgie Fletcher, Brooklyn, New York, Court of Federal Claims No: 18–1574V
42. Paxton T. King, Middleton, Wisconsin, Court of Federal Claims No: 18–1575V
43. Raghu Duggirala, Philadelphia, Pennsylvania, Court of Federal Claims No: 18–1578V
44. Maryam Shahbazian, Santa Clara, California, Court of Federal Claims No: 18–1580V
45. Jennifer Durant, Boston, Massachusetts, Court of Federal Claims No: 18–1581V
46. Carol A. Allen, Easton, Massachusetts, Court of Federal Claims No: 18–1582V
47. Patrick Patterson, Lubbock, Texas, Court of Federal Claims No: 18–1583V
48. Daniel J. Petrie, Arcade, New York, Court of Federal Claims No: 18–1584V
49. Gertrude Smilo on behalf of Joseph G. Smilo, Deceased, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1585V
50. Elizabeth Austin, Boston, Massachusetts, Court of Federal Claims No: 18–1587V
51. Michele Peterson, Webster Groves, Missouri, Court of Federal Claims No: 18–1589V
52. Scott Bowsher and Candy Bowsher on behalf of M. B., Rockville, Indiana, Court

of Federal Claims No: 18–1590V
53. Lisa Sinko, Farmington Hills, Michigan, Court of Federal Claims No: 18–1592V
54. Travis Reitter, Oakland, California, Court of Federal Claims No: 18–1593V
55. Connie Tregle, Lake Charles, Louisiana, Court of Federal Claims No: 18–1596V
56. Scott Skiles and Misty Skiles on behalf of M. S., Boston, Massachusetts, Court of Federal Claims No: 18–1597V
57. Brenda L. Slay, Salina, Kansas, Court of Federal Claims No: 18–1598V
58. Michele Bernardo, West Chester, Pennsylvania, Court of Federal Claims No: 18–1599V
59. Lisa Whitehead-Williams, Chicago, Illinois, Court of Federal Claims No: 18–1600V
60. Linda Chervenok, Paterson, New Jersey, Court of Federal Claims No: 18–1601V
61. Andres Nieves, Novi, Michigan, Court of Federal Claims No: 18–1602V
62. Jimmie L. Foster, Asheville, North Carolina, Court of Federal Claims No: 18–1605V
63. Jesus Romo-Villanueva, Tucson, Arizona, Court of Federal Claims No: 18–1609V
64. Frances Basler, Spokane Valley, Washington, Court of Federal Claims No: 18–1614V
65. Richard Brieseacher, Mount Vernon, Illinois, Court of Federal Claims No: 18–1616V
66. Deborah Ann Dunatov, Douglasville, Georgia, Court of Federal Claims No: 18–1617V
67. Carol McCarvell, Austin, Texas, Court of Federal Claims No: 18–1618V
68. Kelsey Rathjen, Littleton, Colorado, Court of Federal Claims No: 18–1619V
69. Dawn Brooks, Millville, New Jersey, Court of Federal Claims No: 18–1620V
70. Michele Nelson Ruppert, San Francisco, California, Court of Federal Claims No: 18–1621V
71. Michael Francesco, Maiden, North Carolina, Court of Federal Claims No: 18–1622V
72. Robert G. Canady and Sita S. Canady on behalf of A.G.C., Fredericksburg, Virginia, Court of Federal Claims No: 18–1624V
73. Roy Romero, San Antonio, Texas, Court of Federal Claims No: 18–1625V
74. William Lederer, Norwalk, Connecticut, Court of Federal Claims No: 18–1627V
75. Allison Ferrini on behalf of W.F., Morton Grove, Illinois, Court of Federal Claims No: 18–1628V
76. Patricia Moore on behalf of Dr. Timonthy Moore, Deceased, Phoenix, Arizona, Court of Federal Claims No: 18–1629V
77. Glenda Lee Stewart, Chicago, Illinois, Court of Federal Claims No: 18–1630V
78. Cheryl Kraemer, Madison Heights, Michigan, Court of Federal Claims No: 18–1631V
79. Douglas F. Crawford, Panorama City, California, Court of Federal Claims No: 18–1632V
80. William S. Boylston, McMinnville, Oregon, Court of Federal Claims No: 18–1634V
81. Nancy Henderson, Myrtle Creek, Oregon, Court of Federal Claims No: 18–1635V
82. Helen Marie Pell, Indianapolis, Indiana, Court of Federal Claims No: 18–1636V
83. Virginia Powell, Dallas, Texas, Court of Federal Claims No: 18–1638V
84. Kathleen Mitzner, Livingston, Montana, Court of Federal Claims No: 18–1639V
85. Azusa Nash on behalf of U.C.N., Richmond, Virginia, Court of Federal Claims No: 18–1640V
86. Christopher W. Lindbloom, Richmond, Virginia, Court of Federal Claims No: 18–1642V
87. Francesca Ohanian, Foster City, California, Court of Federal Claims No: 18–1643V
88. Rebecca Huffman, Fort Wayne, Indiana, Court of Federal Claims No: 18–1646V
89. Brenda Rae Smith, Bethesda, Maryland, Court of Federal Claims No: 18–1648V
90. Betty Jeter on behalf of Estate of Rexford N. Jeter, Deceased, Montgomery, Alabama, Court of Federal Claims No: 18–1649V
91. Tina Walker, Fredericksburg, Pennsylvania, Court of Federal Claims No: 18–1650V
92. Rosanne Ledet, Washington, District of Columbia, Court of Federal Claims No: 18–1651V
93. Nancy Spotanski, Ballwin, Missouri, Court of Federal Claims No: 18–1653V
94. Gareth Acton, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1654V
95. John R. Harnisch, Pleasant Prairie, Wisconsin, Court of Federal Claims No: 18–1656V
96. Kristine Rucker-Morrow, Chicago, Illinois, Court of Federal Claims No: 18–1657V
97. Cecilia Ruzzene, Knoxville, Tennessee, Court of Federal Claims No: 18–1658V
98. Claudine Carter, South Euclid, Ohio, Court of Federal Claims No: 18–1659V
99. Sheree Kaufman, Greensboro, North Carolina, Court of Federal Claims No: 18–1661V
100. Angela Holt, Stafford, Virginia, Court of Federal Claims No: 18–1662V
101. Anne Jacqueline Kite, Spotsylvania, Virginia, Court of Federal Claims No: 18–1663V
102. Eric Larson, Columbia, Maryland, Court of Federal Claims No: 18–1666V
103. Robert Tafuri, Marlborough, Massachusetts, Court of Federal Claims No: 18–1667V
104. Dawn Halley, Cranbury, New Jersey, Court of Federal Claims No: 18–1668V
105. Madeleine Soares, Dallas, Texas, Court of Federal Claims No: 18–1669V
106. Karlee Tessmer, Pewaukee, Wisconsin, Court of Federal Claims No: 18–1672V
107. Tonya Clark, Junction City, Kansas, Court of Federal Claims No: 18–1673V
108. Martha Walker, Ocean City, New Jersey, Court of Federal Claims No: 18–1674V
109. Deborah Flynn, Annapolis, Maryland, Court of Federal Claims No: 18–1675V
110. Cecilia Nuss, St. Charles, Illinois, Court of Federal Claims No: 18–1676V
111. Debra H. Childress, Midlothian, Virginia, Court of Federal Claims No: 18–1677V
112. Tamra K. Craig, Westfield, Indiana, Court of Federal Claims No: 18–1678V
113. Mary Finch, Chipley, Florida, Court of Federal Claims No: 18–1680V
114. Joan Neptune, Franklin, Tennessee, Court of Federal Claims No: 18–1681V
115. Lindsey Miller, Los Angeles, California, Court of Federal Claims No: 18–1682V
116. April L. Strang-Kutay, Lancaster, Pennsylvania, Court of Federal Claims No: 18–1683V

[FR Doc. 2018–26760 Filed 12–10–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nominations to the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Assistant Secretary for Health (OASH) is seeking nominations of qualified individuals to be considered for appointment as members of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). ACBTSA is a Federal advisory committee within the Department of Health and Human Services. Management support for the activities of this Committee is the responsibility of the OASH. The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration of appointment as members of the ACBTSA. Members of the Committee, including the Chair, are appointed by the Secretary. Members are invited to serve on the Committee for up to four-year terms.

DATES: All nominations must be received no later than 4:00 p.m. ET on Friday, December 28 2018 at the address listed below.

ADDRESSES: All nominations should be sent to the ACBTSA email address at *ACBTSA@hhs.gov.* Alternatively, nominations can be mailed or delivered to: Mr. James Berger, Senior Advisor for Blood and Tissue Policy, Office of Assistant Secretary for Health, Department of Health and Human Services, 330 C Street SW, Room L001 Switzer Building, Washington, DC 20201. Telephone: (202) 795–7608; Email *ACBTSA@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Senior Advisor for Blood and Tissue Policy. Contact information for Mr. Berger is provided above.

A copy of the Committee charter and roster of the current membership can be obtained by contacting Mr. Berger or by

accessing the ACBTSA website at *http://www.hhs.gov/bloodsafety*.

SUPPLEMENTARY INFORMATION: The ACBTSA provides advice to the Secretary through the Assistant Secretary for Health. The Committee advises on a range of policy issues to include: (1) Broad public health, ethical and legal issues related to transfusion and transplantation safety, (2) risk communications related to blood transfusion and tissue transplantation, and (3) the identification of public health issues that affect the availability of blood, blood products, and tissues.

The Committee consists of 23 voting members; 14 public members, including the Chair, and nine (9) individuals designated to serve as official representative members. The public members are selected from State and local organizations, patient advocacy groups, provider organizations, academic researchers, ethicists, physicians, surgeons, scientists, risk communication experts, consumer advocates, and from among communities of persons who are frequent recipients of blood or blood products or who have received tissues or organs. The nine individuals who are appointed as official representatives are selected to serve the interests of the blood, blood products, tissue and organ professional organizations or business sectors. The representative members are selected from the following groups: The AABB (formerly the American Association of Blood Banks); American Association of Tissue Banks; Eye Bank Association of America; Association of Organ Procurement Organizations; and one of either the American Red Cross or America's Blood Centers. The Committee composition can include additional representation from either the plasma protein fraction community or a trade organization; a manufacturer of blood, plasma, or other tissue/organ test kits; a manufacturer of blood, plasma or other tissue/organ equipment; a major hospital organization; or a major hospital accreditation organization. Where more than one company produces a specified product or process, representatives from those companies shall rotate on the same schedule as public members.

All ACBTSA members are authorized to receive the prescribed per diem allowance and reimbursement for travel expenses that are incurred to attend meetings and conduct Committee-related business, in accordance with Standard Government Travel Regulations. Individuals who are appointed to serve as public members are authorized also to receive a stipend for attending Committee meetings and to carry out other Committee-related business. Individuals who are appointed to serve as representative members for a particular interest group or industry are not authorized to receive a stipend for the performance of these duties.

This announcement is to solicit nominations of qualified candidates to five public member positions on the ACBTSA.

Nominations

In accordance with the charter, persons nominated for appointment as members of the ACBTSA should be among authorities knowledgeable in blood banking, tissue banking, transfusion medicine, organ or tissue transplantation, plasma therapies, transfusion and transplantation safety, bioethics, socioeconomics, health policy/law, and/or related disciplines. Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration of appointment: (a) The name, return address, daytime telephone number and affiliation(s) of the individual being nominated, the basis for the individual's nomination, the category for which the individual is being nominated, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the Committee; (b) the name, return address, and daytime telephone number at which the nominator may be contacted. Organizational nominators must identify a principal contact person in addition to the contact; and (c) a copy of a current curriculum vitae or resume for the nominated individual.

Individuals can nominate themselves for consideration of appointment to the Committee. All nominations must include the required information. Incomplete nominations will not be processed for consideration. The letter from the nominator and certification of the nominated individual must bear original signatures; reproduced copies of these signatures are not acceptable.

The Department is legally required to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal Advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of Federal advisory committees. Individuals appointed to serve as public members of Federal advisory committees are classified as special government employees (SGEs). SGEs are government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of the ACBTSA are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: October 19, 2018.

James J. Berger,

Senior Advisor for Blood and Tissue Policy, Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability.

[FR Doc. 2018–26756 Filed 12–10–18; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Monograph on the Systematic Review of Evidence of Long-Term Neurological Effects Following Acute Exposure to the Organophosphorus Nerve Agent Sarin; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces availability of the Draft NTP Monograph on the Systematic Review of Evidence of Long-Term Neurological Effects Following Acute Exposure to the Organophosphorus Nerve Agent Sarin for public comment prior to peer review. In partnership with the National

Institutes of Health (NIH) Countermeasures Against Chemical Threats (CounterACT) Program, the Office of Health Assessment and Translation (OHAT), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), conducted a systematic review to evaluate the evidence of long-term neurological damage in humans after acute, sub-lethal exposure to sarin. The date for the peer review is not yet set; however, it is anticipated to occur in early 2019. The peer-review meeting will be held by webcast only and open to the public; registration will be required for attendance by webcast and to present oral comments. Information about the meeting and registration is available at *https://ntp.niehs.nih.gov/go/36051.*

DATES:

Meeting: When set, the peer-review meeting date will be announced on the meeting web page at *https://ntp.niehs.nih.gov/go/36051* along with deadlines for registration to present oral public comments and to view the webcast. The anticipated timeframe is early 2019.

NTP will also announce the meeting date in an email Listserv notice. Persons can subscribe to news updates at *https://tools.niehs.nih.gov/webforms/index.cfm/main/formViewer/form_id/361.*

Document Availability: The draft NTP monograph should be available by December 5, 2018, at *https://ntp.niehs.nih.gov/go/36051.*

Written Public Comment Submissions: Deadline is January 17, 2019.

Registration for Oral Comments: Please monitor the meeting web page at *https://ntp.niehs.nih.gov/go/36051* for updates pertaining to the oral public comment registration deadline.

Registration to View Webcast: Please monitor the meeting web page at *https://ntp.niehs.nih.gov/go/36051* for updates pertaining to the webcast registration deadline.

ADDRESSES:

Meeting Location: Webcast.

Meeting web page: The draft NTP monograph, preliminary agenda, registration, and other meeting materials will be available at *https://ntp.niehs.nih.gov/go/36051.*

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Ms. Canden Byrd, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293–1660, Fax: (919) 293–1645, Email: *NTP-Meetings@icf.com.*

SUPPLEMENTARY INFORMATION:

Background: OHAT serves as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as ''substances'') cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels.

Sarin is a highly toxic organophosphorus nerve agent that was developed for chemical warfare during World War II and continues to be used as a weapon. The draft NTP monograph presents the results of the systematic review to evaluate the evidence for long-term neurological effects in humans following acute, sub-lethal exposure to sarin with consideration of human, experimental animal, and mechanistic date.

Long-term neurological effects of acute exposure to sarin are not well characterized. Previous reviews of potential health effects of sarin have generally not assessed individual study quality or considered multiple evidence streams (human, animal, and mechanistic data). In addition, the interpretation of effects of sarin in some previous reviews was compounded by concurrent exposure to multiple chemicals, such as assessments of health effects in military personnel during the Gulf War or other conflicts.

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Please monitor the meeting web page at *https://ntp.niehs.nih.gov/go/36051* for updates pertaining to the webcast registration deadline. Individuals with disabilities who need accommodation to view the webcast should contact Canden Byrd by phone: (919) 293–1660 or email: *NTP-Meetings@icf.com.* TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites written and oral public comments on the draft NTP monograph that address scientific or technical issues. Guidelines for public comments are at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

The deadline for submission of written comments is January 17, 2019. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific or technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda will allow for one oral public comment period (up to 12 commenters, up to 5 minutes per speaker). The deadline for registration to provide oral comments will be announced at *https://ntp.niehs.nih.gov/go/36051* after the meeting date is set. Registration will be on a first-come, first-served basis. Each organization will be allowed one time slot. Oral comments will be presented by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified approximately one week before the peer-review meeting about the actual time allotted per speaker.

If possible, oral public commenters will be asked to send a copy of their slides and/or statement or talking points to Canden Byrd by email: *NTP-Meetings@icf.com* by the registration deadline.

Meeting Materials: The draft NTP monograph and preliminary agenda will be available on the NTP website at *https://ntp.niehs.nih.gov/go/36051*. The draft NTP monograph should be available by December 5, 2018. Additional information will be posted when available or may be requested in hardcopy, contact Canden Byrd by phone: (919) 293–1660 or email: *NTP-Meetings@icf.com*. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing

information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Canden Byrd by email: *NTP-Meetings@icf.com*. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: November 28, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–26745 Filed 12–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request National Cancer Institute (NCI) Future Fellows Resume Databank

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Angela Jones, Program Coordinator, Center for Cancer Training, National Cancer Institute, 9609 Medical Center Drive, Room 2W–236, Bethesda, Maryland, 20892 or call non-toll-free number (240) 276–5659 or Email your request, including your address to: *jonesangel@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on August 13, 2018, page 40071 (83 FR 40071) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: National Cancer Institute Future Fellows Resume Databank, 0925–XXXX, Exp., Date XX/XXXX, EXISTING COLLECTION IN USE WITHOUT OMB NUMBER, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute, Center for Cancer Training mission is to catalyze the development of the 21st century workforce capable of advancing cancer research through a scientifically integrated approach. This is accomplished by, (1) coordinating and providing research training and career development activities for fellows and trainees in NCI's laboratories, clinics, and other research groups, (2) developing, coordinating, and implementing opportunities in support of cancer research training, career development, and education at institutions nationwide, and (3) identifying workforce needs in cancer research and adapting NCI's training and career development programs and funding opportunities to address these needs. The proposed information collection involves a website to collect and maintain resumes of interested candidates to be considered for postdoctoral fellowships and internships in science. After posting their resume in the database, NCI Scientists can view and select candidates for current fellowship and internship opportunities offered at NCI.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 200 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Category of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Individual	200	2	30/60	200
Totals	200	400		200

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2018–26765 Filed 12–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Initial Review Group; Mental Health Services Research Committee.

Date: February 27, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6136, MSC 9606, Bethesda, MD 20852, 301–443–1225, *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: December 6, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–26764 Filed 12–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0102]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Freedom of Information/Privacy Act Request

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until February 11, 2019.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0102 in the body of the letter, the agency name and Docket ID USCIS–2008–0028. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0028;

(2) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW, Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2008–0028 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the 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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Freedom of Information/Privacy Act Request.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G–639; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form G–639 and the Freedom of Information Act Immigration Records SysTem (FIRST) e-filing process are provided as a convenient means for individuals to provide data necessary for identification of a particular record being requested under the Freedom of Information/Privacy Act (FOIA/PA).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form G–639 is 165,818 and the estimated hour burden per response is .67 hours; the estimated total number of respondents for the information collection FIRST (e-filing) is 41,455 and the estimated hour burden per response is .5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 131,825 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual

cost burden associated with this collection of information is $2,445,821.

Dated: December 4, 2018.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2018–26726 Filed 12–10–18; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0009]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Petition for Nonimmigrant Worker

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until January 10, 2019.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *dhsdeskofficer@omb.eop.gov.* All submissions received must include the agency name and the OMB Control Number 1615–0009 in the subject line.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on August 30, 2018, at 83 FR 44295, allowing for a 60-day public comment period. USCIS did not receive any comment(s) in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2005–0030 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the 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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–129; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. USCIS uses the data collected on this form to determine eligibility for the requested nonimmigrant petition and/or requests to extend or change nonimmigrant status. An employer (or agent, where applicable) uses this form to petition USCIS for an alien to temporarily enter as a nonimmigrant. An employer (or agent, where applicable) also uses this form to request an extension of stay or change of status on behalf of the alien worker. The form serves the purpose of standardizing requests for nonimmigrant workers, and ensuring that basic information required for assessing eligibility is provided by the petitioner while requesting that beneficiaries be classified under certain nonimmigrant employment categories. It also assists USCIS in compiling information required by Congress annually to assess effectiveness and utilization of certain nonimmigrant classifications.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form I–129 is 530,457 and the estimated hour burden per response is 2.34 hours; the estimated total number of respondents for the information collection E–1/E–2 Classification Supplement to Form I–129 is 4,410 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection Trade Agreement Supplement to Form I–129 is 7,817 and the estimated hour burden per response is 0.67 hours; the estimated total number of respondents for the information collection H Classification Supplement to Form I–129 is 422,130 and the estimated hour burden per response is 2 hours; the estimated total number of respondents for the information collection H–1B and H–1B1 Data Collection and Filing Fee Exemption Supplement is 403,153 and the estimated hour burden per response is 1 hours; the estimated total number of respondents for the information collection L Classification Supplement to Form I–129 is 44,182 and the estimated hour burden per response is 1.34 hours; the estimated total number of respondents for the information collection O and P Classifications Supplement to Form I–129 is 35,999 and the estimated hour burden per response is 1 hours; the estimated total number of respondents for the

information collection Q–1 Classification Supplement to Form I–129 is 183 and the estimated hour burden per response is 0.34 hours; the estimated total number of respondents for the information collection R–1 Classification Supplement to Form I–129 is 8,366 and the estimated hour burden per response is 2.34 hours; the estimated total number of respondents for the information collection Biometrics is 142 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 2,611,882 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $86,668,611.

Dated: December 4, 2018.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2018–26728 Filed 12–10–18; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0051]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Monthly Report on Naturalization Papers

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until February 11, 2019.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0051 in the body of the letter, the agency name and Docket ID USCIS–2005–0032. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2005–0032;

(2) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW, Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2005–0032 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the 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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Monthly Report on Naturalization Papers.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–4; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, local or Tribal Government. This form is used by the clerk of courts that administer the oath of allegiance for naturalization to notify the USCIS of all persons to whom the oath was administered. The information is used by the USCIS to update its alien files and records to indicate that the aliens are now citizens; develop an audit trail on the certificates of naturalization; and determine the payments to be made to the courts for reimbursement of their expenses in connection with the naturalization process.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–4 is 160, it is estimated that each respondent will respond an average of 12 times a year, and the estimated hour burden per response is 0.5 hour.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 960 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $7,200.

Dated: December 4, 2018.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2018–26727 Filed 12–10–18; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6135–N–01]

Rental Assistance Demonstration: Amendment to Final Notice

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner and Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: This notice announces a change to the Rental Assistance Demonstration (RAD) regarding conversions to project-based rental assistance under RAD's Second Component.

DATES: The RAD Supplemental Notice, PIH 2018–22/H 2018–11, is operative December 11, 2018.

ADDRESSES: Interested persons are invited to submit questions or comments electronically to *rad@hud.gov.*

FOR FURTHER INFORMATION CONTACT: To assure a timely response, please direct requests for further information electronically to the email address *rad@hud.gov.* Written requests may also be directed to the following address: Office of Housing—Office of Recapitalization; Department of Housing and Urban Development; 451 7th Street SW, Room 6230; Washington, DC 20410.

SUPPLEMENTARY INFORMATION:

I. Background

RAD, initially authorized by the Consolidated and Further Continuing Appropriations Act, 2012 (Pub. L. 122–55, signed November 18, 2011) (2012 Appropriations Act), allows for the conversion of assistance under the public housing, Rent Supplement (Rent Supp), Rental Assistance (RAP), Moderate Rehabilitation (Mod Rehab), and Mod Rehab Single Room Occupancy (SRO) programs (collectively, ''covered programs'') to long-term, renewable assistance under the Section 8 project based voucher (PBV) or project based rental assistance (PBRA) programs. The most recent version of the RAD program notice is PIH 2012–32/Housing 2017–03, REV–3, which has been amended by supplemental guidance published July 2, 2018, is located at *https://www.hud.gov/sites/dfiles/Housing/documents/RAD_Notice_Rev3_Amended_by_RSN_7-2018.pdf.*

This notice announces the posting of a second supplement to the most current notice PIH 2012–32/Housing 2017–03 REV–3 (RAD Supplemental Notice 3.B, PIH 2018–22/H 2018–11). As provided by the RAD Statute (Section 237 of Title II, Division L, Transportation, Housing and Urban Development, and Related Agencies, of the Consolidated Appropriations Act, 2018, Pub. L. 115–141), this notice addresses the requirement that the demonstration may proceed after HUD publishes the terms of the notice in the **Federal Register**. This notice summarizes the key changes made to the PIH 2012–32/Housing 2017–03 REV–3 through the RAD Supplemental Notice, PIH 2018–22/H 2018–11.

II. Key Changes

In order to maximize the resources available to make property improvements for low-income households living in properties converting under the Second Component of RAD and to align RAD requirements more closely with the underlying PBRA statutory and regulatory requirements related to the Davis-Bacon Act of 1931, the Supplemental Program Notice clarifies that execution of a PBRA contract as a result of the conversion of Rent Supp, RAP, Mod Rehab, or Mod Rehab SRO contracts through RAD after the publication of this notice does not trigger Davis-Bacon prevailing wage requirements.

III. Revised Program Notice Availability

The RAD Supplemental Notice (PIH 2018–22/H 2018–11) can be found on RAD's website, *www.hud.gov/RAD.*

IV. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50, which implemented section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available for public inspection during regular business hours in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the FONSI by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339.

Dated: November 28, 2018.

Dominique Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

Brian D. Montgomery,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2018–26709 Filed 12–10–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2018–0083; FXIA16710900000–178–FF09A30000]

Foreign Endangered Species; Marine Mammals; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA) and foreign or native species for which the Service has jurisdiction under the Marine Mammal Protection Act (MMPA). With some exceptions, the ESA and the MMPA prohibit activities with listed species unless Federal authorization is acquired that allows such activities. The ESA and MMPA also require that we invite public comment before issuing permits for activities involving endangered species or marine mammals.

DATES: We must receive comments by January 10, 2019.

ADDRESSES:

Obtaining Documents: The applications, application supporting

materials, and any comments and other materials that we receive will be available for public inspection at *http://www.regulations.gov* in Docket No. FWS–HQ–IA–2018–0083.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2018–0083.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2018–0083; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2104, via email at *DMAFR@fws.gov,* or via the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Please make your requests or comments as specific as possible, confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments on *http://www.regulations.gov,* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and section 104(c) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA and MMPA prohibit activities with listed species unless Federal authorization is acquired that allows such activities. Permits issued under section 10 of the ESA allow activities for scientific purposes or to enhance the propagation or survival of the affected species. Regulations regarding permit issuance under the ESA are in title 50 of the Code of Federal Regulations in part 17. ESA permits cover a wide range of activities pertaining to foreign listed species, including activities related to the captive-breeding of such species here in the United States. Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

III. Permit Applications

We invite comments on the following applications.

A. Endangered Species

Applicant: Field Museum of Natural History, Chicago, IL; Permit No. 93295C

The applicant requests a permit to import scientific samples of ocelot (*Leopardus pardalis mitis*), jaguar (*Panthera onca*), and South American tapir (*Tapirus terrestris*) from Brazil for the purposes of scientific research. This notification is for a single import.

Applicant: Wild Cat Education & Conservation Fund, Occidental, CA; Permit No. 97801C

The applicant requests a permit to purchase a captive-born snow leopard (*Uncia uncia*) from Tanganyika Wildlife Park, Goddard, KS, for the purpose of enhancing the propagation or survival of the species. This notification is for a single transfer.

Applicant: James Madison University, Harrisonburg, VA; Permit No. 88299C

The applicant requests a permit to import scientific samples of Verreaux's sifaka (*Propithecus verreauxi*) from Madagascar for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Wildlife Conservation Society, Bronx, NY; Permit No. 99617C

The applicant requests a permit to export two male and two female captive-bred African wild dogs (*Lycaon pictus*) to Canada for the purpose of enhancing the propagation or survival of the species. This notification is for a single export.

Applicant: Indiana University-Purdue University Fort Wayne, Fort Wayne, IN; Permit No. 80987C

The applicant requests a permit to import scientific samples of leatherback sea turtles (*Dermochelys coriacea*) from Equatorial Guinea for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: U.S. Fish and Wildlife Service, Abingdon, VA; Permit No. 85964C

The applicant requests a permit to export wild Lee County cave isopods (*Lirceus usdaglun*) taken in Lee County, VA, to University Claude Bernard Lyon, Villeurbanne Cedex, France, for the purpose of scientific research. This notification is for a single export.

Applicant: University of Wisconsin—Madison, Madison, WI; Permit No. 93299C

The applicant requests authorization to import biological samples from captive-bred and wild orangutans (*Pongo pygmaeus*) from multiple locations for the purpose of enhancing the propagation or survival of the species through scientific research. This

notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Eastern Connecticut State University, Willimantic, CT; Permit No. 00760D

The applicant requests a permit to import biological samples of wild roseate terns (*Sterna dougallii dougallii*) from Canada for the purpose of scientific research. This notification is for a single import.

Applicant: Forrest Simpson, Conroe, TX; Permit No. 99011C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for barasingha (*Rucervus duvaucelii*), which is listed at 50 CFR 17.11(h) as swamp deer (*Cervus duvauceli*), to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Zoological Society of San Diego, San Diego, CA; Permit No. 93568C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following families: *Bufonidae, Accipitridae, Alcedinidae, Anatidae, Cacatuidae Cathartidae, Columbidae, Cracidae, Gruidae, Megapodiidae, Phasianidae, Psittacidae, Rallidae, Rhynochetidae, Spheniscidae, Sturnidae, Threskiornithidae, Antilocapridae, Artiodactyla, Bovidae, Canidae, Callithricidae, Cercopithecidae, Cervidae, Moschidae, Daubentoniidae, Elephantidae, Equidae, Felidae, Hominidae, Hylobatidae, Indridae, Lemuridae, Macropodidae, Potoroidae, Pteropodidae, Rhinocerotidae, Tapiridae, Ursidae, Crocodylidae, Gavialidae, Geoemydidae,* and *Iguanidae,* excluding *Cyclura lewisi, Testudinidae,* and *Varanidae,* to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common Name	Scientific Name
Panamanian golden frog	*Atelopus zeteki.*
harpy eagle	*Harpia harpyja.*
Guam kingfisher	*Todiramphus cinnamominus.*
Laysan duck	*Anas laysanensis.*
white-winged duck	*Asarcornis scutulata.*
white cockatoo	*Cacatua alba.*
Andean condor	*Vultur gryphus.*
pink pigeon	*Nesoenas mayeri.*
blue-billed curassow	*Crax alberti.*
red-crowned crane	*Grus Japonensis.*
Maleo	*Macrocephalon maleo.*
Blyth's tragopan	*Tragopan blythii blythii.*
Edward's pheasant	*Lophura edwardsi.*
Palawan peacock-pheasant.	*Polyplectron napoleonis.*
blue-throated conure	*Pyrrhura cruentata.*
Cuban Amazon	*Amazona leucocephala leucocephala.*
great green macaw	*Ara ambiguus ambiguus.*
blue-throated macaw	*Ara glaucogularis.*
Military macaw	*Ara militaris.*
scarlet-chested parrot	*Neophema splendida.*
salmon-crested cockatoo	*Cacatua moluccensis.*
Guam rail	*Hypotaenidia owstoni.*
Kagu	*Rhynochetos jubatus.*
African penguin	*Spheniscus demersus.*
Bali myna	*Leucopsar rothschildi.*
Waldrapp Ibis	*Geronticus eremita.*
Baja pronghorn	*Antilocapra americana peninsularis.*
lowland Anoa	*Bubalus depressicornis.*
Addax	*Addax nasomaculatus.*
Addra gazelle	*Nanger dama ruficollis.*
Arabian oryx	*Oryx leucoryx.*
Bontebok	*Damaliscus pygargus pygargus.*
Cuvier's gazelle	*Gazella cuvieri.*
Indian gaur	*Bos frontalis gaurus.*
Javan banteng	*Bos Javanicus javanicus.*
Scimitar-horned oryx	*Oryx dammah.*
Slender-horned gazelle	*Gazella leptoceros leptoceros.*
Zambesi lechwe	*Kobus leche leche.*
Chinese dhole	*Cuon alpinus lepturus.*
Maned wolf	*Chrysocyon brachyurus.*
golden lion Tamarin	*leontopithecus rosalia.*
golden-headed lion tamarin.	*leontopithecus chrysomelas.*
Francois' langur	*Trachypithecus francoisi.*
Gelada baboon	*Theropithecus gelada.*
lion-tailed Macaque	*Macaca silenus.*
Mandrill	*Mandrillus sphinx.*
Bactrian wapiti	*Cervus elaphus bactrianus.*
Barasingha	*Rucervus duvaucelii duvaucelii.*
Barbary red deer	*Cervus elaphus barbarus.*
Burmese Thamin	*Rucervus eldii thamin.*
Mandarin sika	*Cervus nippon mandarinus.*
Southern Pudu	*Pudu puda.*
Siberian musk deer	*Moschus moschiferus moschiferus.*
Aye-Aye	*Daubentonia madagascariensis.*
African bush elephant	*Loxodonta africana africana.*
Ceylon elephant	*Elephas maximus maximus.*
Indian elephant	*Elephas maximus indicus.*
Grevy's zebra	*Equus grevyi.*
Przewalski's wild horse	*Equus caballus przewalskii.*
Somali wild ass	*Equus africanus somaliensis.*
Amur leopard	*Panthera pardus orientalis*
Black-footed cat	*Felis nigripes.*
clouded leopard	*Neofelis nebulosa nebulosa.*
African lion	*Panthera leo melanochaita.*
Malayan tiger	*Panthera tigris Jacksoni.*
snow leopard	*Uncia uncia.*
cheetah	*Acinonyx jubatus.*
tiger	*Panthera tigris.*
Bonobo	*Pan paniscus.*
Bornean orangutan	*Pongo pygmaeus.*
Sumatran orangutan	*Pongo abelii.*
Western Lowland gorilla	*Gorilla gorilla gorilla.*
red-cheeked gibbon	*Nomascus gabriellae.*
Siamang	*Symphalangus syndactylus.*
Coquerel's Sifaka	*Propithecus coquereli.*
black-and-white ruffed lemur.	*Varecia variegata variegata.*
blue-eyed black lemur	*Eulemur flavifrons.*
red ruffed lemur	*Varecia rubra.*
red-collared lemur	*Eulemur collaris.*
ring-tailed lemur	*Lemur catta.*
pygmy slow Loris	*Nycticebus pygmaeus.*
Parma wallaby	*Macropus parma.*
Southern yellow-footed rock wallaby.	*Petrogale xanthopus xanthopus.*
Koala	*Phascolarctos cinereus.*
Woylie	*Bettongia penicillata.*
Rodrigues flying fox	*Pteropus rodricensis.*
black rhinoceros	*Diceros bicornis.*
Great Indian rhinoceros	*Rhinoceros unicornis.*
Southern white rhinoceros.	*Ceratotherium simum simum.*
Baird's tapir	*Tapirus bairdii.*
Malayan tapir	*Tapirus indicus indicus.*
giant panda	*Ailuropoda melanoleuca.*
Chinese alligator	*Alligator sinensis.*
slender-snouted crocodile	*Mecistops cataphractus.*
dwarf crocodile	*Osteolaemus tetraspis.*
Gharial	*Gavialis gangeticus.*
spotted pond turtle	*Geoclemys hamiltonii.*
river terrapin	*Batagur baska.*
Fijian banded iguana	*Brachylophus bulabula.*
Grand Cayman blue iguana.	*Cyclura lewisi.*
Jamaican iguana	*Cyclura collei.*
Galapagos tortoise	*Chelonoidis nigra.*
radiated tortoise	*Astrochelys radiata.*
Komodo dragon	*Varanus komodoensis.*

Applicant: Uno Mas Ranch LLC, Brandera, TX; Permit No. 99164C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for Arabian oryx (*Oryx leucoryx*) to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Audubon Nature Institute, New Orleans, LA; Permit No. 86989C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for African wild dogs (*Lycaon pictus*), babirusa (*Babyrousa babyrussa*), swamp deer (*Cervus duvauceli*), pudu (*Pudu pudu*), Asian elephant (*Elephas maximus*), leopard (*Panthera pardus*), Komodo Island monitor (*Varanus komodoensis*), Sumatran orangutan (*Pongo abelii*), Panamanian golden frog (*Atelopus varius zeteki*), tomistoma (*Tomistoma schlegelii*), and Fiji banded iguana (*Brachylophus fasciatus*) to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: L.A. Waters Ranch, LLC, Utopia, TX; Permit No. 95637C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for African wild ass (*Equus africanus*) and barasingha (*Rucervus duvaucelii*), which is listed at 50 CFR 17.11(h) as swamp deer (*Cervus duvauceli*), to enhance the propagation

or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants request permits to import sport-hunted trophies of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

Applicant: Jeffery Hammond, Burns, WY; Permit No. 02623D

Applicant: Jeremy Hammond, Cody, WY; Permit No. 02624D

Applicant: Leslie Hathaway, Portland, IN; Permit No. 02625D

Applicant: Michael Dyson, Irving, TX; Permit No. 02612D

Applicant: Matthew Bell, Midland, TX; Permit No. 03114D

Applicant: Charles Bowlin, Shreveport, LA; Permit No. 02359D

Applicant: Donald Pflaum, Cavalier, ND: Permit No. 05672D

B. Marine Mammals

Applicant: U.S. Geological Survey, Alaska Science Center, Anchorage, AK; Permit No. 690038

The applicant requests renewal of a permit to conduct research activities on polar bears (*Ursus maritimus*) in the Southern Beaufort and Chukchi-Bering Seas, and to export and import samples of fat, blood, fur, skin, bones, claws, feces, DNA products, and teeth. This notification covers activities to be conducted by the applicant over a 5-year period.

IV. Next Steps

If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *http://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *http://www.regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations, and the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and its implementing regulations.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2018–26757 Filed 12–10–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A51010.999900]

Land Acquisitions; the Dry Creek Rancheria Band of Pomo Indians, California

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Assistant Secretary—Indian Affairs has made a final determination to acquire 6.14 acres, more or less, into trust for the Dry Creek Rancheria Band of Pomo Indians, California on October 24, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene M. Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1849 C Street NW, MS–4642–MIB, Washington, DC 20240, telephone (202) 208–3615.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual, and is published to comply with the requirement of 25 CFR 151.12(c)(2)(ii) that notice of the decision to acquire land in trust be promptly published in the **Federal Register**. On October 24, 2018, the Assistant Secretary—Indian Affairs issued a decision to accept land in trust for the Dry Creek Rancheria Band of Pomo Indians, California under the authority of Section 5 of the Indian Reorganization Act of 1934 (48 Stat. 984).

Dry Creek Rancheria Band of Pomo Indians, California Sonoma County, California

Legal description containing 6.14 acres, more or less

The Land Referred To Herein Below Is Situated In The State Of California, County Of Sonoma, Unincorporated And Described As Follows:

Parcel One

Being a portion of the Northwest quarter of Section 2, Township 9 North, Range 9 West Mount Diablo Meridian and lying in the Rancho Sotoyome, said portion being more particularly described as follows:

BEGINNING at a 2″ iron pipe on the Township line between Township 10 North, Range 9 West and Township 9 North, Range 9 West, said pipe marks the boundary between the lands of Basalt Rock Company, Inc., recorded in Book 1665 of Official Records, Page 241 and P. and F. Di Regolo, recorded in Book 1634 of Official Records, Page 591; thence South 35°15′ East 1679.33 feet to a 3/4″ iron pipe at the Northerly edge of the Healdsburg-Alexander Valley County Road, at Engineer's Station ''A'' 145 + 01.80; thence along the County Road, South 47°18′30″ West, 21.95 feet; thence South 45°22′30″ West 148.07 feet; thence South 44°18′20″ West 84.12 feet; thence South 48°43′10″ West 110.03 feet; thence North 41°16′50″ West, 4.96 feet; thence South 47°27′ West 200.00 feet; thence North 42°33′ West, 3.32 feet; thence South 47°18′30″ West, 49.0 feet; thence North 42°41′30″ West 3.0 feet; thence South 47°18′30″ West 316.0 feet; thence North 42°41′30″ West, 20.0 feet; thence South 47°18′30″ West, 178.11 feet; thence curving to the right from a tangent that bears South 47°18′30″ West with a radius of 700.00 feet for a distance of 132.0 feet; thence North 31°53′15″ West 30.0 feet; thence curving to the right from a tangent that bears South 58°06′45″ West, with a radius of 670.00 feet for a distance of 125.85 feet to the true point of beginning of the hereinafter described parcel of land.

Beginning at the point above described as the TRUE POINT OF BEGINNING: thence curving to the right along the Northerly edge of the Healdsburg-Alexander Valley County Road, from a tangent that bears South 68°52′30″ West, with a radius of 670.0 feet for a distance of 450.92 feet; thence North 76°10′10″ West, 79.51 feet; thence North 72°33′50″ West 361.76 feet to the lands of McCutchan; thence leaving said County Road, North 1°00′ East 200.33 feet to a ½″ iron pipe; thence leaving the lands of McCutchan, North 89°08′ East 176.72 feet to a ½″ iron pipe; thence South 76°12′ East 229.63 feet to a ½″ iron pipe; thence North 75°53′ East 145.55 feet to a ½″ iron pipe; thence North 85°38′ East 263.37 feet to a ½″ iron pipe; thence South 76°05′ East, 158.33 feet to a ½″ iron pipe; thence South 18°45′ West 294.58 feet to a ½″ iron pipe and the point of beginning.

Parcel Two

A nonexclusive right of way for purposes of ingress and egress over the following described parcel of land:

BEGINNING at the point above described as the true point of beginning; thence North 18°45′ East 294.58 feet to a ½″ iron pipe; thence South 54°18′ East, 222.17 feet to a ½″ iron pipe and the Northerly line of Healdsburg-Alexander Valley County Road; thence South 47°18′30″ West, 57.19 feet along said County Road; thence curving to the right from a tangent that bears South 47°18′30″ West, with a radius of 700.00 feet for a distance of 132.00 feet; thence North 31°53′ 15″ West, 30.00 feet; thence curving to the right from a tangent that bears South 58°06′45″ West with a radius of 670.00 feet for a distance of 125.85 feet to the point of beginning.

Parcel Three

AN EASEMENT of access to the Russian River from all points on the Northerly boundary of the foregoing 6.14 parcel across the lands of Basalt Rock Company, Inc. contiguous to such boundary and said river. BEING the same land and Easements described as Parcel 2 in Deed recorded in Book 1721 of Official Records, at Page 81, Sonoma County Records.

APN: 091–020–016

Dated: October 24, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–26782 Filed 12–10–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19X L1109AF LLUT980300 L12200000.PM0000–24–1A]

Notice of Public Meeting for the Utah Resource Advisory Council/Recreation Resource Advisory Council, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act, the Federal Advisory Committee Act, and the Federal Lands Recreation Enhancement Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Utah Resource Advisory Council (RAC)/Recreation Resource Advisory Council (RRAC) will meet as indicated below.

DATES: The Utah RAC/RRAC will hold a public meeting on January 10 and 11, 2019. The group will meet on January 10, 2019, from 1:00 p.m. to 5:00 p.m. and on January 11, 2019, from 8:00 a.m. to 3:00 p.m.

ADDRESSES: The meeting will be held at the BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101. Written comments may be sent to the BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101.

FOR FURTHER INFORMATION CONTACT: Lola Bird, Public Affairs Specialist, BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101; phone (801) 539–4033; or email *lbird@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 leave a message or question for the above individual. The FRS is available 24 hours a day, seven days a week. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: Agenda topics will include BLM updates from the State Director, the planning efforts for the Grand Staircase-Escalante and Bears Ears National Monuments, Washington County issues, recreation fee proposals, and other planning updates.

A public comment period will take place on January 11, 2019, from 1:00 p.m. to 1:30 p.m., where the public may address the RAC/RRAC. Depending on the number of people who wish to speak, and the time available, the time for individual comments may be limited. Written comments may also be sent to the BLM Utah State Office at the address listed in the **ADDRESSES** section of this notice.

The meeting is open to the public; however, transportation, lodging, and meals are the responsibility of the participating individuals.

Before including your address, phone number, email address, or other personal identifying information in your comments, please 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.

Authority: 43 CFR 1784.4–2.

Anita Bilbao,

Associate State Director.

[FR Doc. 2018–26748 Filed 12–10–18; 8:45 am]

BILLING CODE 4310–DQ–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1068]

Certain Microfluidic Devices; Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding; Extension of Target Date

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the ''Commission'') has determined to review in part the final initial determination (the ''ID'') issued by the presiding administrative law judge (''ALJ'') on September 20, 2018, finding a violation of the Tariff Act of 1930, as amended, in connection with certain asserted patents. The Commission has also determined to extend the target date for the completion of this investigation to February 11, 2019.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–3427. 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, telephone 202–205–1810.

SUPPLEMENTARY INFORMATION: On September 6, 2017, the Commission instituted this investigation based on a complaint filed by Bio-Rad Laboratories, Inc. of Hercules, CA; and Lawrence Livermore National Security, LLC of Livermore, CA (collectively, ''complainants''). 82 FR 42115 (Sept. 6, 2017). The complaint (and supplement thereto) alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337'') based

upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices by reason of infringement of one or more of claims 1–12 and 14–16 of U.S. Patent No. 9,500,664 (''the '664 patent''); claims 1–15 of U.S. Patent No. 9,089,844 (''the '844 patent''); claims 1–21 of U.S. Patent No. 9,636,682 (''the '682 patent''); claims 1–27 of U.S. Patent No. 9,649,635 (''the '635 patent''); and claims 1, 2, 4–8, and 14–21 of U.S. Patent No. 9,126,160 (''the '160 patent). *Id.* The Commission's notice of investigation named as the sole respondent 10X Genomics, Inc. of Pleasanton, CA (''10X''). *Id.* The Office of Unfair Import Investigations was also named as a party to this investigation. *Id.*

On March 6, 2018, the Commission terminated the investigation as to claims 14–17 of the '160 patent; claim 3 of the '664 patent; claims 2, 8, 11, and 14–15 of the '844 patent; claims 2–3 of the '682 patent; and claims 2–4, 9–10, 15, 22, and 27 of the '635 patent. *See* Order No. 12, *unreviewed,* Notice of Commission Determination Not to Review an Initial Determination (Order No. 12) Partially Terminating the Investigation as to Certain Patent Claims (March 6, 2018). On March 26, 2018, the Commission terminated the investigation as to claims 1 and 18 of the '160 patent; claims 6, 7, 9, and 13 of the '844 patent; claims 4 and 13 of the '682 patent; and claims 5 and 17 of the '635 patent. *See* Order No. 16, *unreviewed,* Notice of Commission Determination Not to Review an ID (Order No. 16) Partially Terminating the Investigation as to Certain Patent Claims (March 26, 2018). On April 16, 2018, the Commission terminated the investigation as to claims 2, 6, 7, and 19 of the '160 patent; claims 5–7, 10, and 12 of the '664 patent; claims 1, 3–5, 10, and 12 of the '844 patent; claims 5–6, 8, 10–12, 15, and 20–21 of the '682 patent; and claims 6–8, 11–12, 18–20, and 23–26 of the '635 patent. *See* Order No. 19, *unreviewed,* Notice of Commission Determination Not to Review an Initial Determination (Order No. 19) Partially Terminating the Investigation as to U.S. Patent No. 9,089,844 and Other Asserted Patent Claims (Apr. 16, 2018).

On September 20, 2018, the ALJ issued the ID, which finds 10X in violation of section 337 as to the '664 patent, the '682 patent, and the '635 patent. On September 28, 2018, the ALJ issued her recommendations on remedy, bond, and the public interest. The ALJ recommended that the Commission issue a limited exclusion order directed to 10X's infringing products and a cease and desist order directed to 10X. The ALJ also recommended a bond of 100 percent of entered value during the Presidential review period. *See* 19 U.S.C. 1337(j)(3).

On October 3, 2018, Complainants and 10X each filed petitions for review. OUII did not file a petition for review. On October 11, 2018, the Complainants, 10X, and OUII filed responses to those petitions.

Having examined the record in this investigation, including the ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. In particular, the Commission has determined to review the following:

(1) Whether 10X indirectly infringes the '682 and '635 patents.

(2) Whether 10X's Chip GB infringes claims 1 and 14 of the '664 patent.

(3) Whether 10X's Chip SE infringes claim 20 of the '160 patent and claim 1 of the '664 patent.

As the petitions and responses thereto have adequately addressed these issues, the Commission does not request any briefing on these issues. The Commission has determined to not review the remainder of the ID.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. Complainants are further requested to supply the names of known importers of the products at issue in this investigation. The written submissions and proposed remedial orders must be filed no later than close of business on December 17, 2018. Reply submissions must be filed no later than the close of business on December 24, 2018. Such submissions should address the ALJ's recommended determinations on remedy and bonding and the public interest. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–1068'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/fed_reg_notices/rules/*

handbook_on_electronic_filing.pdf). Persons with 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, solely for cybersecurity purposes (all contract personnel will sign appropriate nondisclosure agreements). All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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: December 4, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–26740 Filed 12–10–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–18–058]

Sunshine Act Meetings

TIME AND DATE: December 14, 2018 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. Nos. 701–TA–598 and 731–TA–1408 (Final)(Rubber Bands from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by December 27, 2018.
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.
Issued: December 7, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–26925 Filed 12–7–18; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States et al. v. The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Western District of North Carolina in *United States and State of North Carolina.* v. *The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas HealthCare System,* Civil Action No. 3:16–cv–00311–RJC–DCK. On June 6, 2016, the United States and the State of North Carolina filed a Complaint alleging that The Charlotte-Mecklenburg Hospital Authority formerly known as Carolinas HealthCare System (or CHS) and now doing business as Atrium Health (''Atrium'') included provisions in its contracts with health insurers that restricted insurers from steering their members to lower-cost, high-quality providers, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The proposed Final Judgment, filed November 15, 2018, enjoins Atrium from (1) enforcing provisions in its current insurer contracts that restrict steering and transparency; (2) having contract provisions with an insurer that would prohibit, prevent or significantly restrain the insurer from using certain steering methods or providing transparency; and (3) penalizing, or threatening to penalize, any insurer for its use of certain steering methods and transparency.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the Western District of North Carolina. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Peter J. Mucchetti, Chief, Healthcare and Consumer Products Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 4100, Washington, DC 20530 (telephone: 202–307–0001).

Patricia A. Brink,

Director of Civil Enforcement.

United States District Court for the Western District of North Carolina Charlotte Division

United States of America and the State of North Carolina, Plaintiffs, v. *The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System,* Defendant.

Case No. 3:16–cv–00311–RJC–DCK
Judge Robert J. Conrad, Jr.

COMPLAINT

The United States of America and the State of North Carolina bring this civil antitrust action to enjoin Defendant, The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas HealthCare System (''CHS''), from using unlawful contract restrictions that prohibit commercial health insurers in the Charlotte area from offering patients financial benefits to use less-expensive healthcare services offered by CHS's competitors. These steering restrictions reduce competition resulting in harm to Charlotte area consumers, employers, and insurers.

I. CHS AND ITS UNLAWFUL STEERING RESTRICTIONS

1. CHS is a North Carolina not-for-profit corporation providing healthcare services with its principal place of business in Charlotte. Its flagship facility is Carolinas Medical Center, a large general acute-care hospital located in downtown Charlotte. It also operates nine other general acute-care hospitals in the Charlotte area.

2. CHS is the dominant hospital system in the Charlotte area, with approximately a 50 percent share of the relevant market, and 2014 revenue of approximately $8.7 billion. Its closest competitor by size is Novant, which owns five general acute care hospitals in the Charlotte area and has less than half

of CHS's revenue. After Novant, the next-largest hospital in the Charlotte area is CaroMont Regional Medical Center, which has less than one tenth of CHS's revenue.

3. CHS exerts market power in its dealings with commercial health insurers (''insurers''). CHS's market power results from its large size, the comprehensive range of healthcare services that it offers, its high market share, and insurers' need to include access to CHS's hospitals–as well as its other facilities and providers–in at least some of their provider networks in insurance plans that cover people in the Charlotte area. CHS's market power is further evidenced by its ability to profitably charge prices to insurers that are higher than competitive levels across a range of services, and to impose on insurers restrictions that reduce competition.

4. CHS's market power has enabled it to negotiate high prices (in the form of high ''reimbursement rates'') for treating insured patients. CHS has long had a reputation for being a high-priced healthcare provider. In a 2013 presentation, CHS's internal strategy group recognized that CHS ''has enjoyed years of annual reimbursement rate increases that are premium to the market, with those increases being applied to rates that are also premium to the market.''

5. Steering is a method by which insurers offer consumers of healthcare services options to reduce some of their healthcare expenses. Steering typically occurs when an insurer offers consumers a financial incentive to use a lower-cost provider or lower-cost provider network, in order to lower their healthcare expenses.

6. Steering–and the competition from lower-priced healthcare providers that steering animates–threatens CHS's high prices and revenues. In 2013, CHS's internal strategy group surveyed a dozen of CHS's senior leaders, asking them to list the ''biggest risks to CHS revenue streams.'' Nine of the twelve leaders polled identified the steering of patients away from CHS as one of the biggest risks to CHS's revenues.

7. To protect itself against steering that would induce price competition and potentially require CHS to lower its high prices, CHS has imposed steering restrictions in its contracts with insurers. These restrictions impede insurers from providing financial incentives to patients to encourage them to consider utilizing lower-cost but comparable or higher-quality alternative healthcare providers.

8. Tiered networks are a popular type of steering that insurers use in healthcare markets. Typically, insurers using tiered networks place healthcare providers that offer better value healthcare services (lower cost, higher quality) in top tiers. Patients who use top-tier providers pay lower out-of-pocket costs. For example, for a procedure costing $10,000, a patient might be responsible for paying $3,600 in coinsurance at a lower-tier hospital, but only $1,800 coinsurance to have the same procedure performed at a top-tier hospital.

9. Narrow-network insurance plans are another popular steering tool. Typically, narrow networks consist of a subset of all the healthcare providers that participate in an insurer's conventional network. A consumer who chooses a narrow-network insurance plan typically pays lower premiums, and lower out-of-pocket expenses than a conventional broad-network insurance plan as long as the consumer is willing to choose from the smaller network of providers for his or her healthcare needs.

10. Providers are motivated to have insurers steer towards them, including through an insurer's narrow or tiered network, because of the increased patient volume that accompanies steering. Thus, the ability of insurers to steer gives providers a powerful incentive to be as efficient as possible, maintain low prices, and offer high quality and innovative services. By doing so, providers induce insurers to steer patient volume to them. Individuals and employers that provide health insurance to their employees benefit tremendously from this because they can lower their healthcare expenses.

11. CHS has gained patient volume from insurers steering towards CHS, and has obtained higher revenues as a result. CHS encourages insurers to steer patients toward itself by offering health insurers modest concessions on its market-power driven, premium prices.

12. However, CHS forbids insurers from allowing CHS's competitors to do the same. CHS prevents insurers from offering tiered networks that feature hospitals that compete with CHS in the top tiers, and prevents insurers from offering narrow networks that include only CHS's competitors. By restricting its competitors from competing for–and benefitting from–steered arrangements, CHS uses its market power to impede insurers from negotiating lower prices with its competitors and offering lower-premium plans.

13. CHS also imposes restrictions in its contracts with insurers that impede insurers from providing truthful information to consumers about the value (cost and quality) of CHS's healthcare services compared to CHS's competitors. CHS's restrictions on insurers' price and quality transparency are an indirect restriction on steering, because they prevent patients from accessing information that would allow them to make healthcare choices based on available price and quality information.

14. Because CHS's steering restrictions prevent its competitors from attracting more patients through lower prices, CHS's competitors have less incentive to remain lower priced and to continue to become more efficient. As a result, CHS's restrictions reduce the competition that CHS faces in the marketplace. In the instances in which insurers have steered in other markets and in the few instances in which insurers have steered in the Charlotte area despite CHS's restrictions, insurers have reduced health insurance costs for consumers.

15. Four insurers provide coverage to more than 85 percent of the commerically-insured residents of the Charlotte area. They are: Aetna Health of the Carolinas, Inc., Blue Cross Blue Shield of North Carolina, Cigna Healthcare of North Carolina, Inc., and United Healthcare of North Carolina, Inc.

16. CHS maintains and enforces steering restrictions in its contracts with all four of these insurers. In some instances, the contract language prohibits steering outright. For example, CHS secured a contractual obligation from one insurer that it ''shall not directly or indirectly steer business away from'' CHS. In other instances, the contract language gives CHS the right to terminate its agreement with the insurer if the insurer engages in steering, providing CHS the ability to deny the insurer and its enrollees access to its dominant hospital system unless the steering ends. Although the contractual language that CHS has imposed varies with each insurer, it consistently creates disincentives that deter insurers from providing to their enrollees truthful information about their healthcare options and the benefits of price and quality competition among healthcare providers that the insurers could offer if they had full freedom to steer.

II. RELEVANT MARKET AND COMPETITIVE EFFECTS

17. The sale of general acute care inpatient hospital services to insurers (''acute inpatient hospital services'') is a relevant product market. The market includes sales of such services to insurers' individual, group, fully-insured and self-funded health plans.

18. The relevant market does not include sales of acute inpatient hospital services to government payers, *e.g.,* Medicare (covering the elderly and disabled), Medicaid (covering low-income persons), and TRICARE (covering military personnel and families) because a healthcare provider's negotiations with an insurer are separate from the process used to determine the rates paid by government payers.

19. Acute inpatient hospital services consist of a broad group of medical and surgical diagnostic and treatment services that include a patient's overnight stay in the hospital. Although individual acute inpatient hospital services are not substitutes for each other (*e.g.,* obstetrics is not a substitute for cardiac services), insurers typically contract for the various individual acute inpatient hospital services as a bundle, and CHS's steering restrictions have an adverse impact on the sale of all acute inpatient hospital services. Therefore, acute inpatient hospital services can be aggregated for analytical convenience.

20. There are no reasonable substitutes or alternatives to acute inpatient hospital services. Consequently, a hypothetical monopolist of acute inpatient hospital services would likely profitably impose a small but significant price increase for those services over a sustained period of time.

21. The relevant geographic market is no larger than the Charlotte area. In this Complaint, the Charlotte area means the Charlotte Combined Statistical Area, as defined by the U.S. Office of Management and Budget, which consists of Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties in North Carolina, and Chester, Lancaster, and York counties in South Carolina. The Charlotte area has a population of about 2.6 million people.

22. Insurers contract to purchase acute inpatient hospital services from hospitals

within the geographic area where their enrollees are likely to seek medical care. Such hospitals are typically close to their enrollees' homes or workplaces. Insurers who seek to sell insurance plans to individuals and employers in the Charlotte area must include Charlotte area hospitals in their provider networks because people who live and work in the Charlotte area strongly prefer to obtain acute inpatient hospital services in the Charlotte area. Charlotte area consumers have little or no willingness to enroll in an insurance plan that provides no network access to hospitals located in the Charlotte area.

23. For these reasons, it is not a viable alternative for insurers that sell health insurance plans to consumers in the Charlotte area to purchase acute inpatient hospital services from providers outside the Charlotte area. Consequently, competition from providers of acute inpatient hospital services located outside the Charlotte area would not likely be sufficient to prevent a hypothetical monopolist provider of acute inpatient hospital services located in the Charlotte area from profitably imposing small but significant price increases for those services over a sustained period of time.

24. An insurer selling health insurance plans to individuals and employers in the Charlotte area must have CHS as a participant in at least some of its provider networks, in order to have a viable health insurance business in the Charlotte area. This gives CHS the ability to impose steering restrictions in its contracts with insurers. When CHS negotiates with insurers for CHS's network participation, CHS typically negotiates the prices and terms of participation for acute inpatient hospital services and other healthcare services, such as outpatient, ancillary, and physician services, at the same time, including services that are located outside the Charlotte area. As a result, CHS's anticompetitive steering restrictions typically apply to all the negotiated services.

25. CHS's maintenance and enforcement of its steering restrictions lessen competition between CHS and the other providers of acute inpatient hospital services in the Charlotte area that would, in the absence of the restrictions, likely reduce the prices paid for such services by insurers. Thus, the restrictions help to insulate CHS from competition, by limiting the ability of CHS's competitors to win more commercially-insured business by offering lower prices.

26. Insurers want to steer towards lower-cost providers and to offer innovative insurance plans that steer. For years, insurers have tried to negotiate the removal of steering restrictions from their contracts with CHS, but cannot because of CHS's market power. In the absence of the steering restrictions, insurers would likely steer consumers to lower-cost providers more than their current contracts with CHS presently permit.

27. As a result of this reduced competition due to CHS's steering restrictions, individuals and employers in the Charlotte area pay higher prices for health insurance coverage, have fewer insurance plans from which to choose, and are denied access to consumer comparison shopping and other cost-saving innovative and more efficient health plans that would be possible if insurers could steer freely. Deprived of the option to benefit from choosing more cost-efficient providers, Charlotte area patients incur higher out-of-pocket costs for their healthcare. Insurers are directly harmed by CHS's imposition of steering restrictions.

28. CHS restricts steering to help insulate itself from price competition, which enables CHS to maintain high prices and preserve its dominant position, and not for any procompetitive purpose. Indeed, when asked under oath whether CHS should limit the ability of insurers to offer tiered networks or narrow networks that exclude CHS, Carol Lovin, CHS's Chief Strategy Officer, said that CHS should not. And when asked her view about the possibility of eliminating CHS's steering restrictions, she testified, ''Would I personally be okay with getting rid of them? Yes, I would.'' CHS's steering restrictions do not have any procompetitive effects. CHS can seek to avoid losses of revenues and market share from lower cost competitors by competing to offer lower prices and better value than its competitors, rather than imposing rules on insurers that reduce the benefit to its rivals from competing on price.

III. JURISDICTION, VENUE AND INTERSTATE COMMERCE

29. The Court has subject-matter jurisdiction over this action under Section 4 of the Sherman Act, 15 U.S.C. § 4 (as to the claim by the United States); Section 16 of the Clayton Act, 15 U.S.C. § 26 (as to the claim by the State of North Carolina); and 28 U.S.C. §§ 1331, 1337(a), and 1345.

30. The Court has personal jurisdiction over CHS under Section 12 of the Clayton Act, 15 U.S.C. § 22. CHS maintains its principal place of business and transacts business in this District.

31. Venue is proper under 28 U.S.C. § 1391 and Section 12 of the Clayton Act, 15 U.S.C. § 22. CHS transacts business and resides in this District and the events giving rise to the claims occurred in this District.

32. CHS engages in interstate commerce and in activities substantially affecting interstate commerce. CHS provides healthcare services for which employers, insurers, and individual patients remit payments across state lines. CHS also purchases supplies and equipment that are shipped across state lines, and it otherwise participates in interstate commerce.

IV. CHS'S VIOLATION OF SECTION 1 OF THE SHERMAN ACT

33. Plaintiffs incorporate paragraphs 1 through 32 of this Complaint.

34. CHS has market power in the sale of acute inpatient hospital services in the Charlotte area.

35. CHS has and likely will continue to negotiate and enforce contracts containing steering restrictions with insurers in the Charlotte area. The contracts containing the steering restrictions are contracts, combinations, and conspiracies within the meaning of Section 1 of the Sherman Act, 15 U.S.C. § 1.

36. These steering restrictions have had, and will likely to continue to have, the following substantial anticompetitive effects in the relevant product and geographic market, among others:

a. protecting CHS's market power and enabling CHS to maintain at supracompetitive levels the prices of acute inpatient hospital services;

b. substantially lessening competition among providers in their sale of acute inpatient hospital services;

c. restricting the introduction of innovative insurance products that are designed to achieve lower prices and improved quality for acute inpatient hospital services;

d. reducing consumers' incentives to seek acute inpatient hospital services from more cost-effective providers; and

e. depriving insurers and their enrollees of the benefits of a competitive market for their purchase of acute inpatient hospital services.

37. Entry or expansion by other hospitals in the Charlotte area has not counteracted the actual and likely competitive harms resulting from CHS's steering restrictions. And in the future, such entry or expansion is unlikely to be rapid enough and sufficient in scope and scale to counteract these harms to competition. Building a hospital with a strong reputation that is capable of attracting physicians and patients is difficult, time-consuming, and expensive. Additionally, new facilities and programs, and typically the expansion of existing facilities and programs, are subject to lengthy licensing requirements, and in North Carolina, to certificate-of-need laws.

38. CHS did not devise its strategy of using steering restrictions for any procompetitive purpose. Nor do the steering restrictions have any procompetitive effects. Any arguable benefits of CHS's steering restrictions are outweighed by their actual and likely anticompetitive effects.

39. The challenged steering restrictions unreasonably restrain trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

V. REQUEST FOR RELIEF

40. The United States and the State of North Carolina request that the Court:

a. adjudge that all of the steering restrictions in the contracts between CHS and any insurer violate Section 1 of the Sherman Act, 15 U.S.C. § 1;

b. enjoin CHS, its officers, directors, agents, employees, and successors, and all other persons acting or claiming to act on its behalf, directly or indirectly, from seeking, agreeing to, or enforcing any provision in any agreement that prohibits or restricts an insurer from engaging, or attempting to engage, in steering towards any healthcare provider;

c. enjoin CHS from retaliating, or threatening to retaliate, against any insurer for engaging or attempting to engage in steering; and

d. award Plaintiffs their costs in this action and such other relief as the Court may deem just and proper.

Dated: June 9, 2016

Respectfully Submitted,

FOR PLAINTIFF UNITED STATES OF AMERICA

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United States District Court for the Western District of North Carolina Charlotte Division

United States of America and State of North Carolina, Plaintiffs, v. *The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System,* Defendant.

Case No. 3:16–cv–00311–RJC–DCK
Judge Robert J. Conrad, Jr.

[PROPOSED] FINAL JUDGMENT

WHEREAS, Plaintiffs, the United States of America and the State of North Carolina (collectively ''Plaintiffs''), filed their Complaint on June 9, 2016; Plaintiffs and Defendant The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health f/k/a Carolinas HealthCare System (collectively the ''Parties''), by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

AND WHEREAS, this Final Judgment does not constitute any evidence against or admission by any party regarding any issue of fact or law;

AND WHEREAS, the Plaintiffs and Defendant agree to be bound by the provisions of this Final Judgment pending its approval by this Court;

AND WHEREAS, the essence of this Final Judgment is to enjoin Defendant from prohibiting, preventing, or penalizing steering as defined in this Final Judgment;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

The Court has jurisdiction over the subject matter of and each of the Parties to this action. The Complaint states a claim upon which relief may be granted against Defendant under Section 1 of the Sherman Act, as amended, 15 U.S.C. § 1.

II. DEFINITIONS

For purposes of this Final Judgment, the following definitions apply:

A. ''Benefit Plan'' means a specific set of health care benefits and Healthcare Services that is made available to members through a health plan underwritten by an Insurer, a self-funded benefit plan, or Medicare Part C plans. The term ''Benefit Plan'' does not include workers' compensation programs, Medicare (except Medicare Part C plans), Medicaid, or uninsured discount plans.

B. ''Carve-out'' means an arrangement by which an Insurer unilaterally removes all or substantially all of a particular Healthcare Service from coverage in a Benefit Plan during the performance of a network-participation agreement.

C. ''Center of Excellence'' means a feature of a Benefit Plan that designates Providers of certain Healthcare Services based on objective quality or quality-and-price criteria in order to encourage patients to obtain such Healthcare Services from those designated Providers.

D. ''Charlotte Area'' means Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties in North Carolina and Chester, Lancaster, and York counties in South Carolina.

E. ''Co-Branded Plan'' means a Benefit Plan, such as Blue Local with Carolinas HealthCare System, arising from a joint venture, partnership, or a similar formal type of alliance or affiliation beyond that present in broad network agreements involving value-based arrangements between an Insurer and Defendant in any portion of the Charlotte Area whereby both Defendant's and Insurer's brands or logos appear on marketing materials.

F. ''Defendant'' means The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health f/k/a Carolinas HealthCare System, a North Carolina hospital authority with its headquarters in Charlotte, North Carolina; and its directors, commissioners, officers, managers, agents, and employees; its successors and assigns; and any controlled subsidiaries (including Managed Health Resources), divisions, partnerships, and joint ventures, and their directors, commissioners, officers, managers, agents, and employees; and any Person on whose behalf Defendant negotiates contracts with, or consults in the negotiation of contracts with, Insurers. For purposes of this Final Judgment, an entity is controlled by Defendant if Defendant holds 50% or more of the entity's voting securities, has the right to 50% or more of the entity's profits, has the right to 50% or more of the entity's assets on dissolution, or has the contractual power to designate 50% or more of the directors or trustees of the entity. Also for purposes of this Final Judgment, the term ''Defendant'' excludes MedCost LLC and MedCost Benefits Services LLC, but it does not exclude any Atrium Health director, commissioner, officer, manager, agent, or employee who may also serve as a director, member, officer, manager, agent, or employee of MedCost LLC or MedCost Benefit Services LLC when such director, commissioner, officer, manager, agent, or employee is acting within the course of his or her duties for Atrium Health. MedCostLLC and MedCost Benefits Services LLC will remain excluded from the definition of ''Defendant'' as long as Atrium does not acquire any greater ownership interest in these entities than it has at the time that this Final Judgment is lodged with the Court.

G. ''Healthcare Provider'' or ''Provider'' means any Person delivering any Healthcare Service.

H. ''Healthcare Services'' means all inpatient services (*i.e.,* acute-care diagnostic and therapeutic inpatient hospital services), outpatient services (*i.e.,* acute-care diagnostic and therapeutic outpatient services, including but not limited to ambulatory surgery and radiology services), and professional services (*i.e.,* medical services provided by physicians or other licensed medical professionals) to the extent offered by Defendant and within the scope of services covered on an in-network basis pursuant to a contract between Defendant and an Insurer. ''Healthcare Services'' does not mean management of patient care, such as through population health programs or employee or group wellness programs.

I. ''Insurer'' means any Person providing commercial health insurance or access to Healthcare Provider networks, including but not limited to managed-care organizations, and rental networks (*i.e.,* entities that lease, rent, or otherwise provide direct or indirect access to a proprietary network of Healthcare Providers), regardless of whether that entity bears any risk or makes any payment relating to the provision of healthcare. The term ''Insurer'' includes Persons that provide Medicare Part C plans, but does not include Medicare (except Medicare Part C plans), Medicaid, or TRICARE, or entities that otherwise contract on their behalf.

J. ''Narrow Network'' means a network composed of a significantly limited number of Healthcare Providers that offers a range of Healthcare Services to an Insurer's members for which all Providers that are not included in the network are out of network.

K. ''Penalize'' or ''Penalty'' is broader than ''prohibit'' or ''prevent'' and is intended to include any contract term or action with the likely effect of significantly restraining steering through Steered Plans or Transparency. In determining whether any contract provision or action ''Penalizes'' or is a ''Penalty,'' factors that may be considered include: the facts and circumstances relating to the contract provision or action; its economic impact; and the extent to which the contract provision or action has potential or actual procompetitive effects in the Charlotte Area.

L. ''Person'' means any natural person, corporation, company, partnership, joint

venture, firm, association, proprietorship, agency, board, authority, commission, office, or other business or legal entity.

M. ''Reference-Based Pricing'' means a feature of a Benefit Plan by which an Insurer pays up to a uniformly-applied defined contribution, based on an external price selected by the Insurer, toward covering the full price charged for a Healthcare Service, with the member being required to pay the remainder. For avoidance of doubt, a Benefit Plan with Reference-Based Pricing as a feature may permit an Insurer to pay a portion of this remainder.

N. ''Steered Plan'' means any Narrow Network Benefit Plan, Tiered Network Benefit Plan, or any Benefit Plan with Reference-Based Pricing or a Center of Excellence as a component.

O. ''Tiered Network'' means a network of Healthcare Providers for which (i) an Insurer divides the in-network Providers into different sub-groups based on objective price, access, and/or quality criteria; and (ii) members receive different levels of benefits when they utilize Healthcare Services from Providers in different sub-groups.

P. ''Transparency'' means communication of any price, cost, quality, or patient experience information directly or indirectly by an Insurer to a client, member, or consumer.

III. APPLICABILITY

This Final Judgment applies to Defendant, as defined above, and all other Persons in active concert with, or participation with, Defendant who receive actual notice of this Final Judgment by personal service or otherwise.

IV. PROHIBITED CONDUCT

A. The contract language reproduced in Exhibit A is void, and Defendant shall not enforce or attempt to enforce it. The contract language reproduced in Exhibit B shall not be used to prohibit, prevent, or penalize Steered Plans or Transparency, but could remain enforceable for protection against Carve-outs. For the Network Participation Agreement between Blue Cross and Blue Shield of North Carolina and Defendant's wholly-owned subsidiary Managed Health Resources, effective January 1, 2014, as amended, Defendant shall exclude from the calculation of total cumulative impact pursuant to Section 6.14 of that agreement any impact to Defendant resulting from Blue Cross and Blue Shield of North Carolina disfavoring Defendant through Transparency or through the use of any Steered Plan.

B. For Healthcare Services in the Charlotte Area, Defendant will not seek or obtain any contract provision which would prohibit, prevent, or penalize Steered Plans or Transparency including:

1. express prohibitions on Steered Plans or Transparency;

2. requirements of prior approval for the introduction of new benefit plans (except in the case of Co-Branded Plans); and

3. requirements that Defendant be included in the most-preferred tier of Benefit Plans (except in the case of Co-Branded Plans). However, notwithstanding this Paragraph IV(B)(3), Defendant may enter into a contract with an Insurer that provides Defendant with the right to participate in the most-preferred tier of a Benefit Plan under the same terms and conditions as any other Charlotte Area Provider, provided that if Defendant declines to participate in the most-preferred tier of that Benefit Plan, then Defendant must participate in that Benefit Plan on terms and conditions that are substantially the same as any terms and conditions of any then-existing broad-network Benefit Plan (*e.g.,* PPO plan) in which Defendant participates with that Insurer. Additionally, notwithstanding Paragraph IV(B)(3), nothing in this Final Judgment prohibits Defendant from obtaining any criteria used by the Insurer to (i) assign Charlotte Area Providers to each tier in any Tiered Network; and/or (ii) designate Charlotte Area Providers as a Center of Excellence.

C. Defendant will not take any actions that penalize, or threaten to penalize, an Insurer for (i) providing (or planning to provide) Transparency, or (ii) designing, offering, expanding, or marketing (or planning to design, offer, expand, or market) a Steered Plan.

I. PERMITTED CONDUCT

A. Defendant may exercise any contractual right it has, provided it does not engage in any Prohibited Conduct as set forth above.

B. For any Co-Branded Plan or Narrow Network in which Defendant is the most-prominently featured Provider, Defendant may restrict steerage within that Co-Branded Plan or Narrow Network. For example, Defendant may restrict an Insurer from including at inception or later adding other Providers to any (i) Narrow Network in which Defendant is the most-prominently featured Provider, or (ii) any Co-Branded Plan.

C. With regard to information communicated as part of any Transparency effort, nothing in this Final Judgment prohibits Defendant from reviewing its information to be disseminated, provided such review does not delay the dissemination of the information. Furthermore, Defendant may challenge inaccurate information or seek appropriate legal remedies relating to inaccurate information disseminated by third parties. Also, for an Insurer's dissemination of price or cost information (other than communication of an individual consumer's or member's actual or estimated out-of-pocket expense), nothing in the Final Judgment will prevent or impair Defendant from enforcing current or future provisions, including but not limited to confidentiality provisions, that (i) prohibit an Insurer from disseminating price or cost information to Defendant's competitors, other Insurers, or the general public; and/or (ii) require an Insurer to obtain a covenant from any third party that receives such price or cost information that such third party will not disclose that information to Defendant's competitors, another Insurer, the general public, or any other third party lacking a reasonable need to obtain such competitively sensitive information. Defendant may seek all appropriate remedies (including injunctive relief) in the event that dissemination of such information occurs.

V. REQUIRED CONDUCT

Within fifteen (15) business days of entry of this Final Judgment, Defendant, through its designated counsel, must notify in writing Aetna, Blue Cross and Blue Shield of North Carolina, Cigna, MedCost, and UnitedHealthcare, that:

A. This Final Judgment has been entered (enclosing a copy of this Final Judgment) and that it prohibits Defendant from entering into or enforcing any contract term that would prohibit, prevent, or penalize Steered Plans or Transparency, or taking any other action that violates this Final Judgment; and

B. For the term of this Final Judgment Defendant waives any right to enforce any provision listed in Exhibit A and further waives the right to enforce any provision listed in Exhibit B to prohibit, prevent, or penalize Steered Plans and Transparency.

VII. COMPLIANCE

A. It shall be the responsibility of the Defendant's designated counsel to undertake the following:

1. within fifteen (15) calendar days of entry of this Final Judgment, provide a copy of this Final Judgment to each of Defendant's commissioners and officers, and to each employee whose job responsibilities include negotiating or approving agreements with Insurers for the purchase of Healthcare Services, including personnel within the Managed Health Resources subsidiary (or any successor organization) of Defendant;

2. distribute in a timely manner a copy of this Final Judgment to any person who succeeds to, or subsequently holds, a position of commissioner, officer, or other position for which the job responsibilities include negotiating or approving agreements with Insurers for the purchase of Healthcare Services, including personnel within the Managed Health Resources subsidiary (or any successor organization) of Defendant; and

3. within sixty (60) calendar days of entry of this Final Judgment, develop and implement procedures necessary to ensure Defendant's compliance with this Final Judgment. Such procedures shall ensure that questions from any of Defendant's commissioners, officers, or employees about this Final Judgment can be answered by counsel (which may be outside counsel) as the need arises. Paragraph 21.1 of the Amended Protective Order Regarding Confidentiality shall not be interpreted to prohibit outside counsel from answering such questions.

B. For the purposes of determining or securing compliance with this Final Judgment, or any related orders, or determining whether the Final Judgment should be modified or vacated, and subject to any legally-recognized privilege, from time to time authorized representatives of the United States or the State of North Carolina, including agents and consultants retained by the United States or the State of North Carolina, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division or the Attorney General for the State of North Carolina, and on reasonable notice to Defendant, be permitted:

1. access during Defendant's office hours to inspect and copy, or at the option of the

United States, to require Defendant to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendant, relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendant's officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendant.

C. Within 270 calendar days of entry of this Final Judgment, Defendant must submit to the United States and the State of North Carolina a written report setting forth its actions to comply with this Final Judgment, specifically describing (1) the status of all negotiations between Managed Health Resources (or any successor organization) and an Insurer relating to contracts that cover Healthcare Services rendered in the Charlotte Area since the entry of the Final Judgment, and (2) the compliance procedures adopted under Paragraph VII(A)(3) of this Final Judgment.

D. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division or the Attorney General for the State of North Carolina, Defendant shall submit written reports or responses to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

E. The United States may share information or documents obtained under Paragraph VII with the State of North Carolina subject to appropriate confidentiality protections. The State of North Carolina shall keep all such information or documents confidential.

F. No information or documents obtained by the means provided in Paragraph VII shall be divulged by the United States or the State of North Carolina to any Person other than an authorized representative of (1) the executive branch of the United States or (2) the Office of the North Carolina Attorney General, except in the course of legal proceedings to which the United States or the State of North Carolina is a party (including grand jury proceedings), for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

G. If at the time that Defendant furnishes information or documents to the United States or the State of North Carolina, Defendant represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendant marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States and the State of North Carolina shall give Defendant ten (10) calendar days' notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

H. For the duration of this Final Judgment, Defendant must provide to the United States and the State of North Carolina a copy of each contract and each amendment to a contract that covers Healthcare Services in the Charlotte Area that it negotiates with any Insurer within thirty (30) calendar days of execution of such contract or amendment. Defendant must also notify the United States and the State of North Carolina within thirty (30) calendar days of having reason to believe that a Provider which Defendant controls has a contract with any Insurer with a provision that prohibits, prevents, or penalizes any Steered Plans or Transparency.

VIII. Retention of Jurisdiction

The Court retains jurisdiction to enable any Party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

IX. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendant agrees that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of the decree and the appropriateness of any remedy therefor by a preponderance of the evidence, and Defendant waives any argument that a different standard of proof should apply.

B. The Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore all competition Plaintiffs alleged was harmed by the challenged conduct. Defendant agrees that it may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either Party as the drafter.

C. In any enforcement proceeding in which the Court finds that Defendant has violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against Defendant, whether litigated or resolved prior to litigation, Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as any other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

X. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment shall expire ten (10) years from the date of its entry, except that after five (5) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendant that the continuation of the Final Judgment is no longer necessary or in the public interest.

XI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The Parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, any comments thereon, and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16]

Robert J. Conrad, Jr.
United States District Judge.

Exhibit A

Aetna

Section 2.8 of the Physician Hospital Organization Agreement between and among Aetna Health of the Carolinas, Inc., Aetna Life Insurance Company, Aetna Health Management, LLC, and Defendant states in part:

''Company may not . . . steer Members away from Participating PHO Providers other than instances where services are not deemed to be clinically appropriate, subject to the terms of Section 4.1.3 of this Agreement.''

In addition, Section 2.11 of the above-referenced agreement states in part:

''Company reserves the right to introduce in new Plans . . . and products during the term of this Agreement and will provide PHO with ninety (90) days written notice of such new Plans, Specialty Programs and products. . . . For purposes under (c) and (d) above, Company commits that Participating PHO Providers will be in-network Participating Providers in Company Plans and products as listed on the Product Participation Schedule. If Company introduces new products or benefit designs in PHO's market that have the effect of placing Participating PHO Providers in a non-preferred position, PHO will have the option to terminate this Agreement in accordance with Section 6.3. Notwithstanding the foregoing, if Company introduces an Aexcel performance network in PHO Provider's service area, all PHO Providers will be placed in the most preferred benefit level. As long as such Plans or products do not directly or indirectly steer Members away from a Participating PHO Provider to an alternative Participating Provider for the same service in the same level of care or same setting, the termination provision would not apply.''

Blue Cross and Blue Shield of North Carolina

The Benefit Plan Exhibit to the Network Participation Agreement between Blue Cross and Blue Shield of North Carolina and

Defendant (originally effective January 1, 2014), as replaced by the Fifth Amendment, states in part:

''After meeting and conferring, if parties cannot reach agreement, then, notwithstanding Section 5.1, this Agreement will be considered to be beyond the initial term, and you may terminate this Agreement upon not less than 90 days' prior Written Notice to us, pursuant to Section 5.2.''

Cigna

Section II.G.5 of the Managed Care Alliance Agreement between Cigna HealthCare of North Carolina, Inc. and Defendant states in part:

''All MHR entities as defined in Schedule 1 will be represented in the most preferred benefit level for any and all CIGNA products for all services provided under this Agreement unless CIGNA obtains prior written consent from MHR to exclude any MHR entities from representation in the most preferred benefit level for any CIGNA product. . . . As a MHR Participating Provider, CIGNA will not steer business away from MHR Participating Providers.''

Medcost

Section 3.6 of the Participating Physician Hospital Organization agreement between Medcost, LLC and Defendant states in part:

''Plans shall not directly or indirectly steer patients away from MHR Participating Providers.''

UnitedHealthcare

Section 2 of the Hospital Participation Agreement between UnitedHealthcare of North Carolina, Inc. and Defendant states in part:

''As a Participating Provider, Plan shall not directly or indirectly steer business away from Hospital.''

Exhibit B

Cigna

Section II.G.5 of the Managed Care Alliance Agreement between Cigna HealthCare of North Carolina, Inc. and Defendant states in part:

''CIGNA may not exclude a MHR Participating Provider as a network provider for any product or Covered Service that MHR Participating Provider has the capability to provide except those carve-out services as outlined in Exhibit E attached hereto, unless CIGNA obtains prior written consent from MHR to exclude MHR Participating Provider as a network provider for such Covered Services.''

UnitedHealthcare

Section 2 of the Hospital Participation Agreement between UnitedHealthcare of North Carolina, Inc. and Defendant states in part:

''Plan may not exclude Hospital as a network provider for any Health Service that Hospital is qualified and has the capability to provide and for which Plan and Hospital have established a fee schedule or fixed rate, as applicable, unless mutually agreed to in writing by Plan and Hospital to exclude Hospital as a network provider for such Health Service.''

In addition, Section 3.6 of the above-referenced agreement states in part:

''During the term of this Agreement, including any renewal terms, if Plan creates new or additional products, which product otherwise is or could be a Product Line as defined in this Agreement, Hospital shall be given the opportunity to participate with respect to such new Product Line.''

United States District Court for the Western District of North Carolina Charlotte Division

United States of America and the State of North Carolina, Plaintiffs, v. *The Charlotte-Mecklenburg Hospital Authority, d/b/a Carolinas Healthcare System,* Defendant.

Case No. 3:16–cv–00311–RJC–DCK
Judge Robert J. Conrad, Jr.

COMPETITIVE IMPACT STATEMENT

Plaintiff United States of America (''United States''), pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. §§ 16(b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THE PROCEEDING

On June 9, 2016, the United States and the State of North Carolina filed a civil antitrust lawsuit against The Charlotte-Mecklenburg Hospital Authority, formerly known as Carolinas HealthCare System and now doing business as Atrium Health (''Atrium''), to enjoin it from using steering restrictions in its agreements with health insurers in the Charlotte, North Carolina area. The Complaint alleges that Atrium's steering restrictions are anticompetitive and violate Section 1 of the Sherman Act, 15 U.S.C. § 1, because the restrictions have detrimental effects on competition among healthcare providers in the Charlotte area.

Healthcare providers charge health insurers a wide variety of prices for the same service, but insurers have generally not passed these price differences on to consumers because most commercial health plans offer coverage that is the same no matter which provider a patient chooses. This weakens the connection between price and quantity that is the essence of competition because it allows a provider to charge a high price without losing business to rivals. To control escalating healthcare costs, insurers have developed health plans and plan features that ''steer'' members by providing financial incentives that enable members to share savings by choosing more cost-effective providers, which stimulates competition between providers. To enable patients to choose more cost-effective providers, insurers also provide members with transparency about the prices, quality, patient experience, or anticipated out-of-pocket costs at different healthcare providers.

Atrium is the largest health system in the Charlotte area. For an insurer to maintain a competitive health insurance business in the Charlotte area, it needs to have a contractual relationship with Atrium that gives employers and consumers the option of purchasing insurance that covers care there.

Atrium has used its dominant position to demand contractual restrictions on steering and transparency that interfere with the competitive process. Insurers that contract with Atrium are prohibited from providing financial incentives or information that would encourage consumers to obtain healthcare services from competing providers. These contract provisions significantly reduce the number of additional patients that Atrium's competitors can hope to attract by agreeing to lower prices or otherwise providing greater value. These restrictions have been in Atrium's contracts for years, and remain to this day.

Atrium's steering restrictions reduce the competitive incentive that Atrium's competitors would otherwise have to lower prices in order to win more business. This interference in the competitive process has reduced competition between Atrium and other healthcare providers in the Charlotte area. In addition, because many of the most innovative healthcare plans in the country today are based on steering to more efficient providers, Atrium's steering restrictions have also curbed the introduction of such plans, and reduced choices for Charlotte-area consumers.

Plaintiffs and Atrium have entered into a Stipulation and proposed Final Judgment. The proposed Final Judgment enjoins Atrium from (1) enforcing provisions in its current insurer contracts that restrict steering and transparency; (2) seeking or obtaining contract provisions with an insurer that would prohibit, prevent, or penalize the insurer from using popular steering methods or providing transparency; and (3) penalizing, or threatening to penalize, any insurer for its use of these popular steering methods and transparency. The proposed Final Judgment is described in detail beginning with Section III below. In the Stipulation, Atrium agrees to abide by the injunctive provisions of the proposed Final Judgment while awaiting its entry by the Court.

The United States (unless it has withdrawn its consent), the State of North Carolina, and Atrium have stipulated that the Court may enter the proposed Final Judgment at any time after compliance with the APPA. Entry of the proposed Final Judgment would terminate this action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. DESCRIPTION OF THE ALLEGED VIOLATION

A. Atrium and other Charlotte-Area Hospitals

Atrium is the largest healthcare system in North Carolina and one of the largest not-for-profit healthcare systems in the United States. It is the dominant hospital system in the Charlotte area. Its flagship facility is Carolinas Medical Center, a general acute-care hospital located near downtown Charlotte and the largest hospital in North Carolina. Atrium also operates nine additional general acute-care hospitals in the Charlotte area. Atrium owns, manages, or has strategic affiliations with over 40 hospitals in the Carolinas, and sells healthcare services throughout the Carolinas, including in

freestanding emergency departments, urgent care centers, physician practices, outpatient surgery centers, imaging centers, nursing homes, and laboratories. In 2017, Atrium's owned, managed, and affiliated hospitals and other healthcare providers earned net operating revenue of close to $10 billion.

In addition to Atrium's ten Charlotte-area hospitals, there are eleven other general acute-care hospitals in the Charlotte area. The next largest hospital system, Novant Health (''Novant''), owns five general acute-care hospitals located in that area and had operating revenue of approximately $4.6 billion in 2017, making Novant less than half the size of Atrium. Novant's largest hospital in the Charlotte area is Novant Presbyterian Medical Center, which is the second-largest hospital in Charlotte. After Novant, the next-largest hospital in the Charlotte area is CaroMont Regional Medical Center. CaroMont Regional Medical Center is a 370-bed hospital in Gastonia, North Carolina, and is owned and operated by CaroMont Health, an independent community hospital system. In 2016, CaroMont Health had net operating revenue of approximately $529 million. The remaining hospitals in the Charlotte area are operated by Community Health Systems, Inc., Tenet Healthcare Corporation, and Iredell Health System.

B. The Relevant Market

The Complaint alleges that Atrium has market power in a relevant market for the sale of general acute care inpatient hospital services sold to commercial health insurers (''GAC inpatient hospital services'') in the Charlotte area. GAC inpatient hospital services consist of a broad group of medical and surgical diagnostic and treatment services that includes a patient's overnight stay in the hospital. Although individual GAC inpatient hospital services are not substitutes for each other (*e.g.,* a patient who needs heart surgery cannot elect instead to have her knee replaced), GAC inpatient hospital services can be aggregated for analytical convenience because the competitive conditions for each of the individual services is largely the same.

The relevant geographic market for the sale of GAC inpatient hospital services is no larger than the Charlotte area.[1] Insurers contract to purchase GAC inpatient hospital services from hospitals within the geographic area where their members are likely to seek medical care because consumers prefer to seek medical care near the places where they work and live. As a result, insurers doing business in the Charlotte area must include in their provider networks hospitals located in the Charlotte area. Charlotte-area consumers have little or no willingness to enroll in an insurance plan that provides no network access to hospitals located in the Charlotte area. For these reasons, it is not a viable alternative for insurers that sell health plans to consumers in the Charlotte area to contract for GAC inpatient hospital services from providers outside the Charlotte area.

C. Anticompetitive Effects of the Steering Restrictions

1. Atrium is the dominant hospital system in the Charlotte area

Atrium is the dominant seller of GAC inpatient hospital services in the Charlotte area. Atrium has market power in this market. The market for GAC inpatient hospital services in the Charlotte area is highly concentrated, and Atrium's market share is more than 55 percent. By comparison, Atrium's largest rival, Novant Health, has approximately 17 percent of the licensed hospital beds in the Charlotte area. Without an attractive broad-network plan that includes Atrium, insurers would not be viable in the Charlotte area because they would not be able to attract the business of employers. Atrium's size and breadth give it significant market power because it can decline to participate in an insurer's network unless it obtains high prices and advantageous contract terms.

As a result of its market power, Atrium has been able to secure from insurers high prices relative to other hospital systems in the Charlotte area and relative to other advanced medical centers in North Carolina. These higher prices are not explained by any measure of relative high-quality. Because of high provider prices, patients' out-of-pocket healthcare costs in the Charlotte area are among the highest in North Carolina.

2. Steering is part of the competitive process

Employers in Charlotte and elsewhere around the country have approached health insurers about ways to address rising healthcare costs. One approach of increasing interest is the introduction of steering mechanisms into the health plans that employers offer. Steering can be one way of fostering competition among hospitals.

Steering can be accomplished in several ways. Popular types of steering in healthcare are narrow networks and tiered networks, reference-based pricing, and centers of excellence.[2] Transparency into hospitals' or physicians' relative prices and quality is also important to help effectuate steering.

a. Narrow networks and tiered networks

In addition to offering the broad-network plans that are most popular with employers, insurers in Charlotte want to introduce narrow network and tiered insurance options. Narrow networks are formed by using cost and/or quality criteria to select and contract with a subset of healthcare providers in an area. For example, a health plan sold in the Charlotte area that consists of hospitals and physicians only at Novant, CaroMont, and Community Health Systems would be a narrow-network plan. Because using an in-network provider costs a member less than using an out-of-network provider, a consumer that enrolls in a narrow-network plan is choosing to be steered to participating providers. The likely increase in patient volume realized by providers in the narrow network can help the insurer to negotiate lower prices, and then to pass those savings along in the form of lower premiums.

Tiered networks are typically created by designating network providers into different levels (or tiers) based mostly on quality and price. Tiered networks typically have two or more tiers of in-network providers: a preferred tier and one or more secondary in-network tiers. There may also be providers that remain out-of-network. In tiered networks, members are free to use any of the providers, but receive the most substantial benefits when they choose a provider in the preferred tier. This tier typically includes the providers with the best mix of quality and price. Tiered and narrow network plans are increasingly popular with employers and consumers. For example, in 2017, 19 percent of large employers that offered healthcare coverage provided a narrow-network plan to their employees and 31 percent offered a tiered plan.[3] A large majority of the plans offered on the individual healthcare exchanges are narrow network plans. Narrow and tiered networks can effectively reduce healthcare costs and make insurance more affordable.

b. Reference-based pricing and centers of excellence

Reference-based pricing and centers of excellence are forms of steering that can be used as a feature of a health benefit plan. For reference-based pricing, the insurer establishes a market-wide standard, or ''reference,'' price for a service. The reference price can be established by drawing from average local prices or from other sources such as the reimbursement amounts established by Medicare rules. The benefit plan covers the member's expenses up to the ''reference price.'' Reference-based pricing steers members towards the providers that have prices at or below the reference price. This gives higher-priced providers an incentive to reduce their prices to be closer to the reference price.[4]

A center of excellence is a designation that an insurer applies to a provider for its quality and/or cost efficiency in delivering a particular healthcare service. The insurer often provides a financial incentive to consumers to select the center of excellence. For example, an insurer may designate a particular hospital in a metropolitan area as

[1] As used in this case, the Charlotte area means the Charlotte Combined Statistical Area, as defined by the U.S. Office of Management and Budget, which consists of Cabarrus, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties in North Carolina, and Chester, Lancaster, and York counties in South Carolina.

[2] The proposed Final Judgment defines narrow networks, tiered networks, and health plans with reference-based pricing or centers of excellence as ''Steered Plans.''

[3] Kaiser Family Foundation, *2017 Employer Health Benefits Survey,* 213–214, *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[4] The California Public Employees' Retirement System (''CalPERS'') has successfully used reference-based pricing to lower expenses on hip and knee replacements. A study of the first year after implementation of the reference-based pricing program indicates that surgical volumes at low-price facilities increased while volumes at high-price facilities decreased. Prices declined at both high and low price facilities. As a result CalPERS and its employees saved approximately $3 million. James C. Robinson and Timothy T. Brown, *Increases in Consumer Cost Sharing Redirect Patient Volumes and Reduce hospital Prices for Orthopedic Surgery, 32 Health Affairs* 1392, 1394–97 (2013).

its center of excellence in bariatric surgery because the hospital has superior expertise or is particularly cost effective. To incent members to obtain bariatric surgery there, the insurer may reduce or eliminate out-of-pocket expenses for members who choose that hospital. Members remain free to obtain bariatric surgery elsewhere and pay the out-of-pocket expenses prescribed under the plan. Members are steered towards a center of excellence by virtue of the designation and the cost savings.

c. Transparency

Transparency is the communication of price, cost, quality, or patient experience information to a member. Transparency makes steered plans more effective by providing consumers with information to enable them to comparison shop before selecting a provider. Transparency may also be a form of steering even in the absence of differential benefits because information that identifies one provider as more cost effective than another provider may prompt consumers to choose the more cost-effective provider.

3. To insulate itself from competition, Atrium required that steering restrictions be included in its insurer contracts

To protect its dominant share and high prices and insulate itself from competition, Atrium has used its market power to require every major insurer in the Charlotte area—Aetna Health of the Carolinas, Inc. (''Aetna''), Blue Cross and Blue Shield of North Carolina (''BCBS–NC''), Cigna Healthcare of North Carolina, Inc. (''Cigna''), and United Healthcare of North Carolina, Inc. (''UnitedHealthcare'') [5]— to accept contract terms that restrict the insurers from steering their members to Atrium's lower-cost competitors.

Atrium's contracts with each of these insurers contain steering restrictions that either expressly prohibit the insurer from steering their members away from Atrium, or impede steering through other means, such as by imposing a financial penalty on any steering against Atrium that exceeds a specified amount or by allowing Atrium to promptly terminate the insurer's contract if the insurer steers against Atrium. Atrium used its market power to require that insurers agree to these contract provisions that restrict steering, and thereby restrict competition.

Atrium's steering restrictions restrain insurers from offering consumers the choice of narrow-network plans that do not include Atrium, and tiered-network plans that do not place Atrium in the most favorable tier. Atrium's steering restrictions also prevent insurers from offering reference-based pricing because if the reference price for a service is lower than the price that Atrium charges for that service, members will be steered away from Atrium. Insurers are also prevented from offering financial incentives for members to obtain services at non-Atrium providers that are designated centers of excellence.

These restrictions also prevent insurers from providing members transparency into the price, quality, patient experience, and anticipated out-of-pocket costs of Atrium's healthcare services compared to Atrium's competitors. Atrium's restrictions on transparency indirectly restrict steering because they inhibit consumers from accessing information that would allow them to make better-informed healthcare provider choices.

Deprived of any mechanism to reward low prices with more patient volume, insurers cannot create incentives for Atrium's rivals to compete on price. Atrium's steering restrictions, therefore, reduce competition for GAC inpatient hospital services in the Charlotte area by impeding its competitors' ability to attract patients by offering lower prices to insurers and their members. The steering restrictions prevent consumers from benefitting from lower prices, so they protect Atrium from losing patient volume in response to high prices. This reduction in competition causes prices to be higher than they would be in the absence of Atrium's steering restrictions.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The purpose of the proposed Final Judgment is to prevent Atrium from impeding insurers' steered plans and transparency, and to restore competition among healthcare providers in the Charlotte area. The proposed Final Judgment will accomplish this objective through injunctive, compliance, and enforcement provisions.

Atrium has market power in GAC inpatient hospital services, but the proposed Final Judgment applies to the broad range of healthcare services that Atrium provides and to which its steering restrictions apply. The additional healthcare services covered by the proposed Final Judgment include outpatient services (such as ambulatory surgeries and radiological services), professional services rendered by physicians, and ancillary services such as imaging and lab services. The full scope of services covered by the proposed Final Judgment falls within the proposed Final Judgment's definition of ''Healthcare Services.'' Because Atrium uses its market power to restrict steering away from it for any healthcare service, the proposed Final Judgment provides relief that is broader than the set of services in the relevant market.

The proposed Final Judgment also applies to a broad range of benefit plans. This includes health insurance policies sold to individuals, fully-insured and self-funded health plans sold to employers and other groups, and Medicare Advantage plans.

A. Prohibited Conduct

The proposed Final Judgment seeks to restore competition by prohibiting Atrium from engaging in specific conduct. There are three main provisions. The first stops Atrium from enforcing the current contract provisions at issue in this suit. The second stops Atrium from enforcing similar or new contractual provisions that would restrict steering in the Charlotte area. The third stops Atrium from retaliating against insurers for steering in the Charlotte area.

1. Eliminating the anticompetitive contract provisions

The proposed Final Judgment eliminates the contractual language that Plaintiffs alleged is anticompetitive. The proposed Final Judgment voids the contractual provisions listed in Exhibit A to the proposed Final Judgment that expressly prevent steering. For example, a provision stating that an insurer ''will not steer business away from'' Atrium is voided from that insurer's contract. Additionally, a part of a contract between Atrium and an insurer that required the insurer to give Atrium 90 days' notice before bringing a plan to market that would steer patients away from Atrium is also voided. Further, the proposed Final Judgment eliminates a provision in one insurer's contract that allows Atrium to terminate the contract on 90 days' notice if the insurer offers a plan that would steer away from Atrium.

In addition, Atrium's contracts with commercial insurers contain other provisions that require the insurer to include Atrium in all of its benefit plans. Each such provision prevents the insurer from creating narrow networks that feature Atrium's rivals, but exclude Atrium. The proposed Final Judgment lists that language in Exhibit B, and prohibits Atrium from enforcing or attempting to enforce such contractual provisions to prevent, prohibit, or penalize steered plans and transparency.[6]

Finally, the proposed Final Judgment prevents Atrium from enforcing a ''material impact'' provision in its contract with BCBS–NC in a manner that reduces BCBS–NC's incentives to steer to more efficient providers.

2. Preventing new contractual provisions that harm steering

The proposed Final Judgment also prevents Atrium from seeking or obtaining similar or new contract provisions that would prohibit, prevent, or penalize steering through steered plans or transparency in the Charlotte area.

Paragraph IV(B) of the proposed Final Judgment identifies three types of contractual provisions that, among others, would prohibit, prevent, or penalize steering through steered plans and would thus violate the terms of the proposed Final Judgment. First, Atrium may not expressly prohibit

[5] These four major insurers cover over 90 percent of the commercially-insured residents of the Charlotte area. MedCost is the next-largest health plan in the Charlotte area. MedCost provides administrative services and access to its healthcare provider networks to employers that self-fund their employees' healthcare benefits. Employers that are self-funded pay the healthcare benefit claims from the assets of their business, rather than purchase health insurance policies for the benefit of their employees. Atrium owns 50 percent of MedCost.

[6] The contract provisions appearing in Exhibit B could remain enforceable to prevent insurers from ''carving out'' certain Atrium procedures from their benefits plans. A ''carve-out'' is an industry term defined in the proposed Final Judgment as an arrangement by which an insurer unilaterally removes all or substantially all of a particular healthcare service from coverage in a benefit plan during the performance of a network-participation agreement. Insurers are free to negotiate carve-outs as part of a contract, but Atrium may prohibit insurers from carving additional services out of a contract after it is signed.

steered plans or transparency. Second, Atrium may not require prior approval of new benefit plans. Third, Atrium may not demand to be included in the most-preferred tier of benefit plans regardless of price.

The Final Judgment's injunction against steering restrictions also reaches beyond these three existing provisions to include any contract provision that prohibits, prevents, or penalizes steering. ''Penalize'' is a term in the proposed Final Judgment that includes within its definition anything that would significantly restrain an insurer's steering. Because steering away from Atrium necessarily reduces its volume and revenues, terms that punish such reductions with higher prices or other detrimental consequences may be penalties. Whether a provision or action is likely to significantly restrain steering depends on the facts and circumstances, including but not limited to its economic impact, and any procompetitive effects that would tend to lower healthcare costs or otherwise benefit consumers in the Charlotte area.

3. Atrium may not retaliate against steering

Under the terms of the proposed Final Judgment Atrium also may not seek or obtain any contract provision, or take any other action that would penalize an insurer for steering away from Atrium through steered plans or transparency. For example, Atrium may not threaten to terminate its participation in an insurer's healthcare networks because the insurer was planning to introduce a tiered-network plan that steered away from Atrium.

B. Conduct That is Not Prohibited by the Final Judgment

Paragraph V of the proposed Final Judgment sets forth conduct that Atrium may undertake without violating the terms of the proposed Final Judgment. Paragraph V(A) makes clear that nothing in the proposed Final Judgment prohibits Atrium from exercising any of its contractual rights provided it does not engage in any conduct that would violate the terms of the proposed Final Judgment.

If Atrium is the most-prominently featured provider in a narrow-network plan or co-branded plan,[7] Paragraph V(B) of the proposed Final Judgment allows Atrium to restrict an insurer from steering away from Atrium in that plan. Such restrictions may help narrow networks and co-branded plans be more effective, and this provision allows Atrium to participate in plans that steer towards it.

Paragraph V(C) makes clear that the proposed Final Judgment does not prohibit Atrium from negotiating with insurers for the ability to review the information about Atrium that an insurer disseminates through transparency, as long as any provision for review does not delay dissemination of the information. The proposed Final Judgment does not prevent Atrium from challenging information that it believes is inaccurate, including pursuing legal remedies available to it.

Paragraph V(C) also makes clear that the proposed Final Judgment does not prohibit Atrium from seeking certain safeguards regarding the insurer's dissemination of the prices Atrium has negotiated with insurers. Atrium may seek contractual provisions with an insurer prohibiting the insurer from disseminating Atrium's negotiated prices to Atrium's competitors, other insurers, or the general public. Atrium may also seek contractual provisions with an insurer requiring the insurer to obtain a covenant from any third party receiving Atrium's negotiated prices that such third party will not disclose that information to Atrium's competitors, another insurer, the general public, or another third party lacking a reasonable need to know such information. Atrium may also seek all appropriate remedies in the event that dissemination of such information occurs.

C. Required Conduct

The proposed Final Judgment also prescribes conduct that Atrium is required to undertake in order to facilitate prompt and effective relief. Paragraph VI of the proposed Final Judgment requires Atrium to provide Aetna, BCBS–NC, Cigna, MedCost and UnitedHealthcare with a copy of the Final Judgment and notify them in writing within 15 business days of the Court's entry of the proposed Final Judgment that (1) the Final Judgment has been entered; (2) the Final Judgment prohibits Atrium from entering into or enforcing any agreement provision that violates the Final Judgment; (3) Atrium waives the right to enforce any contract language reproduced in Exhibit A; and (4) Atrium waives the right to enforce any contract language reproduced in Exhibit B to the extent such language prohibits, prevents, or penalizes steered plans or transparency.

D. Compliance

Under Paragraph VII of the proposed Final Judgment, within 15 calendar days of the entry of the Final Judgment, Atrium must provide a copy of the Final Judgment to each of its commissioners and officers as well as each employee who has responsibility to negotiate or approve contracts with insurers. Within 60 calendar days of the entry of the proposed Final Judgment, Atrium must develop and implement procedures necessary to ensure Atrium's compliance with the proposed Final Judgment, including procedures to answer questions from Atrium's commissioners and employees about abiding by the terms of the proposed Final Judgment.

Within 270 calendar days of entry of the proposed Final Judgment, Atrium must submit to the United States and the State of North Carolina a written report setting forth its actions to comply with the proposed Final Judgment. Atrium must also submit to the United States and the State of North Carolina a copy of any new or revised agreement or amendment to any agreement with any insurer that is executed during the term of the proposed Final Judgment no later than 30 calendar days after the date the agreement or amendment is executed.

Atrium must also notify the United States and the State of North Carolina within 30 calendar days of having reason to believe that a provider which Atrium controls has a contract with any insurer with a provision that prohibits, prevents, or penalizes transparency or any steered plan.

To facilitate monitoring Atrium's compliance with the proposed Final Judgment, Paragraphs VII(B) and VII(D) of the proposed Final Judgment require Atrium to grant the United States access, upon reasonable notice, to Atrium's records and documents relating to matters contained in the proposed Final Judgment. In addition Atrium must make its employees available for interviews or depositions and answer interrogatories and prepare written reports relating to matters contained in the proposed Final Judgment upon request.

The proposed Final Judgment also contains provisions that promote compliance and make the enforcement of the proposed Final Judgment as effective as possible. Paragraph IX(A) provides that the United States retains and reserves all rights to enforce the provisions of the proposed Final Judgment, including its rights to seek an order of contempt from the Court. Under the terms of this Paragraph, Atrium has agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the proposed Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Atrium has waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance obligations with the standard of proof that applies to the underlying offense that the compliance commitments address.

Paragraph IX(B) sets forth the parties' agreed-upon rules for interpreting the proposed Final Judgment's provisions. Because consent decrees share many attributes with ordinary contracts, they should be construed as contracts for purposes of enforcement. *See Anita's New Mexico Style Mexican Food* v. *Anita's Mexican Foods Corp.,* 201 F.3d 314, 319 (4th Cir. 2000) (quoting *United States* v. *ITT Continental Baking Co.,* 420 U.S. 223, 236–37 (1975)). The parties have agreed that the Court should employ ordinary tools of interpretation to enforce the proposed Final Judgment. In Paragraph IX(B), the parties make clear the purpose of the proposed Final Judgment that can be used as an interpretive tool. The proposed Final Judgment was drafted with the purpose of resolving this litigation and restoring all competition that Plaintiffs alleged was harmed by the challenged conduct. Paragraph IX(B) says that the provisions of the proposed Final Judgment are to be interpreted to give effect to the procompetitive purpose of the federal antitrust laws, and to restore this lost competition.

Atrium also agrees that the Court may enforce any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, *see* Fed.R.Civ.P. 65(d) (requiring specific terms and ''reasonable detail''), even if the provision is not clear and

[7] A co-branded plan is a benefit plan created by a formal and substantial level of alliance or affiliation, such as a partnership or joint venture, between a provider and an insurer. A co-branded plan has the logos of both the insurer and provider on the plan's marketing materials.

unambiguous on its face, by applying these procompetitive principles and ordinary tools of interpretation. *See Martin's Herend Imports, Inc.* v. *Diamond & Gem Trading,* 195 F.3d 765, 771 (5th Cir. 1999) (''The mere fact that interpretation is necessary does not render the injunction so vague and ambiguous that a party cannot know what is expected of him.'' (internal citation and quotation omitted)). When interpreting the proposed Final Judgment, the Court should not construe the language of the proposed Final Judgment against either party as the drafter.

Paragraph IX(C) of the proposed Final Judgment provides that should the Court find in an enforcement proceeding that Atrium has violated the proposed Final Judgment, the United States may apply to the Court for a one-time extension of the proposed Final Judgment, together with such other relief as may be appropriate. In addition, in order to compensate American taxpayers for any costs associated with the investigation and enforcement of violations of the proposed Final Judgment, Paragraph IX(C) further provides that in any successful effort by the United States to enforce the proposed Final Judgment against Atrium, whether litigated or resolved prior to litigation, Atrium agrees to reimburse the United States for attorneys' fees, experts' fees, or costs incurred in connection with any enforcement effort, including the investigation of the potential violation.

Finally, Paragraph X of the proposed Final Judgment provides that the proposed Final Judgment shall expire ten years from the date of its entry, except that after five years from the date of its entry, the proposed Final Judgment may be terminated upon notice by the United States to the Court and Atrium that the continuation of the proposed Final Judgment is no longer necessary or in the public interest.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

Section 4 of the Clayton Act, 15 U.S.C. § 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. § 16(a), the proposed Final Judgment has no *prima facie* effect in any subsequent private lawsuit that may be brought against Atrium.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States, the State of North Carolina, and Atrium have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 calendar days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 calendar days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States Department of Justice, which remains free to withdraw its consent to the entry of the proposed Final Judgment at any time prior to the Court's entry of the judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's internet website and, under certain circumstances, published in the **Federal Register**.

Written comments should be submitted to:

Peter J. Mucchetti
Chief, Healthcare and Consumer Products Section
Antitrust Division
United States Department of Justice
450 Fifth Street, NW, Suite 4100
Washington, DC 20530

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the proposed Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

As an alternative to the proposed Final Judgment, the United States considered continuing this litigation, and proceeding to trial in May 2019 against Atrium. While the proposed Final Judgment represents a negotiated resolution to the action that necessitated compromises by Plaintiffs and Atrium, the United States is satisfied that the relief contained in the proposed Final Judgment will remedy the anticompetitive conduct identified in the Complaint. The proposed Final Judgment would achieve all or substantially all of the relief the United States would have obtained through litigation but avoids the time, expense, and uncertainty of a full trial on the merits.

VII. APPA's STANDARD OF REVIEW FOR THE PROPOSED FINAL JUDGMENT

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States* v. *U.S. Airways Group, Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements).

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the decree is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001). Instead:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[8]

In determining whether a proposed settlement is in the public interest, a district

[8] *See also BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass'').

court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also U.S. Airways,* 38 F. Supp. 3d at 74–75 (noting that a court should not reject the proposed remedies because it believes others are preferable and that room must be made for the government to grant concessions in the negotiation process for settlements); *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant ''due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case''). The ultimate question is whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.''' *Microsoft,* 56 F.3d at 1461. To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, a court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize a court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60. As the court confirmed in *SBC Communications,* courts ''cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power.'' *SBC Commc'ns,* 489 F. Supp. 2d at 15.

In its 2004 amendments,[9] Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11. A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76. *See also United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); S. Rep. No. 93–298 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

[9] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for a court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Respectfully submitted,

Dated: December 4, 2018

FOR PLAINTIFF UNITED STATES OF AMERICA:

John R. Read
Karl D. Knutsen
Natalie Melada
Catherine R. Reilly
David Stolzfus
Paul Torzilli

Antitrust Division, U.S. Department of Justice, 450 Fifth Street NW, Suite 4100, Washington, D.C. 20530, (p) 202/307.0468, John.Read@usdoj.gov.

[FR Doc. 2018–26755 Filed 12–10–18; 8:45 am]

BILLING CODE 4410–11–P

NATIONAL SCIENCE FOUNDATION

Request for Information on National Strategic Overview for Quantum Information Science

AGENCY: National Science Foundation.

ACTION: Notice of request for information.

SUMMARY: The National Science and Technology Council (NSTC) Subcommittee on Quantum Information Science (SCQIS) release of the ''National Strategic Overview for Quantum Information Science'' (hereafter ''Strategic Overview'') calls upon agencies to develop plans to address six key policy areas to enable continued American leadership in quantum information science. The National Science Foundation (NSF), working with the NSTC, is requesting information from the research and development community around quantum information science (QIS) to inform the subcommittee as the Government develops potential means of addressing specific policy recommendations.

DATES: Interested persons are invited to submit comments on or before 11:59 p.m. (ET) on January 25, 2019.

ADDRESSES: Comments submitted in response to this notice may be sent by either of the following methods:

- *Email: nsfscqis@nsf.gov.* Email submissions should be machine-readable and not be copyright-protected. Submissions should include ''RFI Response: National Strategic Overview for Quantum Information Science'' in the subject line of the message.
- *Direct input to the website: http://www.nsfscqis.org*

Instructions: Response to this RFI is voluntary. Each individual or institution is requested to submit only one response. Submissions must not exceed the equivalent of one page for each question, or eight pages total, in 12 point or larger font, with a page number provided on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

Responses to this RFI may be posted online as discussions proceed. Therefore, we request that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT: C. Denise Caldwell at (703)-292–7371 or *nsfscqis@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The National Science and Technology

Council's Subcommittee on Quantum Information Science ''National Strategic Overview for Quantum Information Science'' (hereafter ''Strategic Overview'') was released in September 2018. This document calls upon agencies to develop plans to address six key policy areas to enable continued American leadership in quantum information science. On behalf of Federal agencies the NSTC Subcommittee on Quantum Information Science seeks public input to inform the subcommittee as the Government develops potential means of addressing the specific policy recommendations included in the ''Strategic Overview''. Responders are asked to answer one or more of the following questions:

1. What specific actions could the US Government take that would contribute best to implementing the policy recommendations in the Strategic Overview? What challenges, not listed in section 3, should also be taken into account in implementation of the Strategic Overview recommendations?

2. What are the scientific and technological challenges that, with substantial resources and focus over the next ten years, will transform the QIS research and development landscape?

3. Regarding industrial engagement, what roles can the U.S. Government play in enabling the innovation ecosystem around QIS-related technologies? Are there critical barriers for industrial innovation in this space? How can these barriers be addressed? What role can the U.S. Government play in mitigating early or premature investment risks?

4. How can the U.S. Government engage with academia and other workforce development programs and stakeholders to appropriately train and maintain researchers in QIS while expanding the size and scope of the 'quantum-smart' workforce?

5. What existing infrastructure should be leveraged, and what new infrastructure could be considered, to foster future breakthroughs in QIS research and development?

6. What other activities/partnerships could the U.S. Government use to engage with stakeholders to ensure America's prosperity and economic growth through QIS research and development?

7. How can the United States continue to attract and retain the best domestic and international talent and expertise in QIS?

8. How can the United States ensure that US researchers in QIS have access to cutting-edge international technologies, research facilities, and knowledge?

Reference: National Strategic Overview for Quantum Information Science, https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Strategic-Overview-for-Quantum-Information-Science.pdf.

Submitted by the National Science Foundation in support of the NSTC Subcommittee on Quantum Information Science on December 6, 2018.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2018–26754 Filed 12–10–18; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0156]

Information Collection: NRC Form 748, National Source Tracking Transaction Report

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''NRC Form 748, National Source Tracking Transaction Report.''

DATES: Submit comments by January 10, 2019.

ADDRESSES: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0202), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0156 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–2018–0156. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0156 on this website.

- *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.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML18276A272. The supporting statement is available in ADAMS under Accession No. ML18276A270.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''NRC Form 748, National Source Tracking Transaction Report.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on August 1, 2018, 83 FR 37535.

1. *The title of the information collection:* NRC Form 748, National Source Tracking Transaction Report.
2. *OMB approval number:* 3150–0202.
3. *Type of submission:* Extension.
4. *The form number if applicable:* NRC Form 748.
5. *How often the collection is required or requested:* On occasion (at completion of a transaction, and at inventory reconciliation).
6. *Who will be required or asked to respond:* Licensees that manufacture, receive, transfer, disassemble, or dispose of nationally tracked sources.
7. *The estimated number of annual responses:* 18,927 (13,200 online + 480 batch upload + 5,247 NRC Form 748).
8. *The estimated number of annual respondents:* 1,400 (260 NRC Licensees + 1,140 Agreement State Licensees).
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 1,963.1 hours.
10. *Abstract:* In 2006, the NRC amended its regulations to implement a National Source Tracking System (NSTS) for certain sealed sources. The amendments require licensees to report certain transactions involving nationally tracked sources to the NSTS. These transactions include manufacture, transfer, receipt, disassembly, or disposal of the nationally tracked source. This information collection is mandatory and is used to populate the NSTS. National source tracking is part of a comprehensive radioactive source control program for radioactive materials of greatest concern. The NRC and Agreement States use the information provided by licensees in the NSTS to track the life cycle of the nationally tracked source from manufacture until disposal. NSTS enhances the ability of NRC and Agreement States to conduct inspections and investigations, communicate information to other government agencies, and verify legitimate ownership and use of nationally tracked sources.

Dated at Rockville, Maryland, this 6th day of December 2018.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–26747 Filed 12–10–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0138]

Information Collection: Request for Information Pursuant to 10 CFR 50.54(f) Regarding Recommendations 2.1, 2.3 and 9.3, of the Near Term Task Force Review of Insights From the Fukushima Dai-ichi Event

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, ''Request for Information Pursuant to 10 CFR 50.54(f) Regarding Recommendations 2.1, 2.3 and 9.3, of the Near Term Task Force Review of Insights from the Fukushima Dai-ichi Event.''

DATES: Submit comments by February 11, 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–2018–0138. Address questions about dockets IDs in *Regulations.gov* to Krupskaya Castellon; telephone: 301–287–9221; email: *Krupskaya.Castellon@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: O–2 F21, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: 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*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0138 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–2018–0138. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0138 on this website.
- *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*. A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML12053A340. The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML18254A271 and ML18254A274.
- *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*.

B. Submitting Comments

Please include Docket ID NRC–2018–0138 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:* Request for Information Pursuant to 10 CFR 50.54(f) Regarding Recommendations 2.1, 2.3 and 9.3, of the Near Term Task Force Review of Insights from the Fukushima Dai-ichi event.

2. *OMB approval number:* 3150–0211.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* Once.

6. *Who will be required or asked to respond:* 12 power reactor licensees.

7. *The estimated number of annual responses:* 4 (12 power reactors will each respond once over the course of the three-year clearance period).

8. *The estimated number of annual respondents:* 4 (12 power reactors will each respond once over the course of the three-year clearance period).

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 11,000 hours.

10. *Abstract:* Following events at the Fukushima Dai-Ichi nuclear power plant resulting from the March 11, 2011, earthquake and subsequent tsunami, and in response to requirements contained in section 402 of the Consolidated Appropriations Act (Pub. L. 112–074), the NRC requested information from power reactor licensees pursuant to title 10 of the *Code of Federal Regulations* part 50.54(f). The information requested includes seismic risk assessments and seismic high frequency confirmations. The NRC will use the information provided by licensees to determine if additional regulatory action is necessary. Licensees will have already completed submittals in response to this 50.54(f) request for seismic and flooding walkdown reports, seismic hazard reevaluations, seismic risk assessment, seismic spent fuel pool evaluations, flooding hazard reevaluations, flooding integrated assessments, focused evaluations of local intense precipitation and available physical margin, communications analyses, and initial and final staffing analyses.

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 6th day of December 2018.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–26746 Filed 12–10–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–312; NRC–2018–0180]

Sacramento Municipal Utility District; Rancho Seco Nuclear Generating Station; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: License termination; issuance; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on September 11, 2018, regarding the termination of Operating License (Possession Only) No. DPR–54 for the Rancho Seco Nuclear Generating Station. This action is necessary to replace the first paragraph in the Supplementary Information section with the following: ''The NRC has terminated License No. DPR–54, held by Sacramento Municipal Utility District (SMUD), for Rancho Seco in Herald, California, and has approved the site for unrestricted release. Accordingly, the existing indemnity agreement between SMUD and the NRC has been amended.''

DATES: The correction is effective December 11, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0180 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–2018–0180. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Ted Carter, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5543, email: *Ted.Carter@nrc.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** on September 11, 2018 (83 FR 45994), in FR Doc. 2017–19602, on page 45994, under the **SUPPLEMENTARY INFORMATION** section, the

first paragraph should be replaced with the following: ''The NRC has terminated License No. DPR–54, held by Sacramento Municipal Utility District (SMUD), for Rancho Seco in Herald, California, and has approved the site for unrestricted release. Accordingly, the existing indemnity agreement between SMUD and the NRC has been amended.''

Specifically, the last word (terminated) in the first paragraph, should be replaced with ''amended'' to accurately reflect the action.

Dated at Rockville, Maryland, this 4th day of December 2018.

For the Nuclear Regulatory Commission.

Amy Snyder,

Acting Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–26744 Filed 12–10–18; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84719; File No. SR-CboeBZX–2018–076]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To List and Trade Shares of the FormulaFolios Sector Rotation ETF, a Series of the Northern Lights Fund Trust IV, Under Rule 14.11(i), Managed Fund Shares

December 4, 2018.

I. Introduction

On October 2, 2018, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b-4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the FormulaFolios Sector Rotation ETF (''Fund'') of the Northern Lights Fund Trust IV (''Trust'') under BZX Rule 14.11(i). The proposed rule change was published for comment in the **Federal Register** on October 22, 2018.[3] On November 8, 2018, the Exchange filed Amendment No. 1 to the proposed rule change.[4] On November 30, 2018, the Exchange filed Amendment No. 2 to the proposed rule change.[5] The Commission has received no comments on the proposal. This order grants approval of the proposed rule change, as modified by Amendment Nos. 1 and 2.

II. Exchange's Description of the Proposal, as Modified by Amendment Nos. 1 and 2

The Exchange proposes to list and trade the Shares of the Fund under BZX Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by the Trust, which was established as a Delaware statutory trust on June 2, 2015. The Exchange represents that Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N–1A (''Registration Statement'') with the Commission.[6] FormulaFolio Investments, LLC is the investment adviser to the Fund (''Adviser'').[7]

The Fund will be an actively managed exchange-traded fund that seeks to provide a long-term total return which exceeds the total return of its Primary Benchmark Index.[8] The Fund will seek to achieve its investment objective, under Normal Market Conditions,[9] by utilizing derivatives, or a combination of derivatives and direct investments, to gain 100% equity exposure. The Exchange submits this proposal in order to allow the Fund to hold over-the-counter (''OTC'') derivatives, in a manner that may not comply with BZX Rule 14.11(i)(4)(C)(v), which requires, among other things, that the aggregate gross notional value of OTC derivatives not exceed 20% of the weight of the portfolio (including gross notional exposures).[10] Specifically, the Exchange is proposing that the Fund may hold up to 75% of the weight of its portfolio in OTC derivatives, including gross notional exposures. Otherwise, the Exchange represents that the Fund will comply with all other listing requirements on an initial and continued listing basis under BZX Rule 14.11(i).[11]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84438 (October 16, 2018), 83 FR 53343.

[4] In Amendment No. 1, which amended and replaced the proposed rule change in its entirety, the Exchange: (a) clarified references to certain OTC derivatives that the Fund intends to invest; (b) clarified that, in the event that Sector Swaps (as defined herein) are unavailable or the pricing for such contracts are unfavorable, the Fund may attempt to replicate the desired equity exposure by purchasing some or all of the equity securities that are listed on a U.S. national securities exchange, including ETFs, comprising the top four sectors at the time; and (c) made other non-substantive, technical, and clarifying corrections to the proposal. Because Amendment No. 1 does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues under the Act, Amendment No. 1 is not subject to notice and comment. Amendment No. 1 to the proposed rule change is available at: *https://www.sec.gov/comments/sr-cboebzx-2018-076/srcboebzx2018076-4716147-176694.pdf.*

[5] In Amendment No. 2, the Exchange: (a) Clarified that the Fund will meet the requirements of Rule 14.11(i)(4)(C)(vi), which requires that, to the extent that listed or OTC derivatives are used to gain exposure to individual equities and/or fixed income securities, or to indexes of equities and/or indexes of fixed income securities, the aggregate gross notional value of such exposure shall meet the criteria set forth in BZX Rule 14.11(i)(4)(C)(i) and (ii) (including gross notional exposures), respectively; and (b) made other non-substantive, technical, and clarifying corrections to the proposal. Because Amendment No. 2 does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues under the Act, Amendment No. 2 is not subject to notice and comment. Amendment No. 2 to the proposed rule change is available at: *https://www.sec.gov/comments/sr-cboebzx-2018-076/srcboebzx2018076-4716146-176693.pdf.*

[6] *See* Registration Statement on Form N–1A for the Trust, dated July 27, 2018 (File Nos. 333–204808 and 811–23066). According to the Exchange, the Trust has obtained an order granting certain exemptive relief under the Investment Company Act of 1940 (''1940 Act''). *See* Investment Company Act Release No. 29571 (May 16, 2017) (File No. 812–32367).

[7] The Exchange represents that the Adviser is not a registered broker-dealer and is not currently affiliated with any broker-dealers. In addition, the Exchange represents that Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. In the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of, and/or changes to, the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[8] The Fund's Primary Benchmark Index is the S&P 500 Index.

[9] As defined in BZX Rule 14.11(i)(3)(E), the term ''Normal Market Conditions'' includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or system failures; or force majeure type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[10] BZX Rule 14.11(i)(4)(C)(v) provides that ''the portfolio may, on both an initial and continuing basis, hold OTC derivatives, including forwards, options, and swaps on commodities, currencies and financial instruments (*e.g.,* stocks, fixed income, interest rates, and volatility) or a basket or index of any of the foregoing, however the aggregate gross notional value of OTC derivatives [sic] shall not exceed 20% of the weight of the portfolio (including gross notional exposures).''

[11] In particular, the Exchange notes that the Fund will meet the requirements of BZX Rule 14.11(i)(4)(C)(vi), which requires that, to the extent that listed or OTC derivatives are used to gain exposure to individual equities and/or fixed income securities, or to indexes of equities and/or indexes of fixed income securities, the aggregate gross

Continued

The Adviser will allocate the Fund's assets based on two proprietary investment models. The Adviser's first investment model will identify trends for the individual sectors within its Primary Benchmark Index. Each month, the model will analyze the strength of the US economy and rank the sectors of its Primary Benchmark Index based on a blend of various technical momentum indicators, volatility gauges, and valuation multiples. When the economy appears healthy, sectors with the highest risk-adjusted returns (lower volatility and higher price momentum) and the lowest valuations (lower price ratios) are ranked higher. When the economy appears unhealthy, sectors with more stable price movements and lower volatility are ranked higher. The Fund will invest in the top four sectors in an equal weight. In order to achieve such exposure, the Fund will use OTC swap contracts that reference each applicable sector index (''Sector Swaps'').[12] In the event that such Sector Swaps are unavailable or the pricing for such contracts are unfavorable, the Fund may attempt to replicate the desired equity exposure by purchasing some or all of the equity securities that are listed on a U.S. national securities exchange, including ETFs,[13] comprising the top four sectors at the time.[14] If the model indicates the market is doing poorly, and if not enough sectors pass the screening criteria, the Fund can invest a portion or all of its assets in cash or Cash Equivalents.[15] The Exchange is proposing to allow the Fund to hold up to 75% of the weight of its portfolio (including gross notional exposure) in Sector Swaps, collectively, in a manner that may not comply with 14.11(i)(4)(C)(v).[16]

The Adviser's second investment model is used to manage an active bond allocation exclusively through holding fixed income ETFs. This model analyzes various major fixed income asset classes (U.S. treasuries, investment grade U.S. bonds, high-yield U.S. bonds, high-yield municipal bonds, and floating rate bonds) based on a blend of yield spreads, interest rates, and price momentum. Following the ranking process, the Fund will invest in ETFs based on the highest-ranked asset classes, with the lowest ranked asset classes left out of the Fund.[17] When not enough of the asset classes meet the model's criteria, the Fund may invest heavily in cash or Cash Equivalents until more asset classes become favorable for investing.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares, as modified by Amendment Nos. 1 and 2, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[18] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[19] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act[20] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers and investors of information with respect to quotations for and transactions in securities.

According to the Exchange, apart from the exception to BZX Rule 14.11(i)(4)(C)(v) described above, the Fund's proposed investments will satisfy, on an initial and continued listing basis, all of the generic listing standards under BZX Rule 14.11(i)(4)(C) and all other applicable requirements for Managed Fund Shares under Rule 14.11(i). In addition, the Exchange represents that the Shares of the Fund will comply with all other requirements applicable to Managed Fund Shares including, but not limited to, requirements relating to the dissemination of key information such as the Disclosed Portfolio, Net Asset Value (''NAV''), and the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, firewalls, and the information circular, as set forth in Exchange rules applicable to Managed Fund Shares and the orders approving such rules.

The Exchange also represents that the intra-day, closing, and settlement prices of exchange-traded portfolio assets, including equity securities, will be readily available from the securities exchanges trading such securities, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. Intraday price quotations on OTC swaps and fixed income instruments are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay or in real-time for a paid fee. Price information for Cash Equivalents will be available from major market data vendors. In addition, the Disclosed Portfolio will be available on the issuer's website free of charge. The

notional value of such exposure shall meet the criteria set forth in BZX Rule 14.11(i)(4)(C)(i) and (ii) (including gross notional exposures), respectively.

[12] The Fund will attempt to limit counterparty risk in non-cleared swap contracts by entering into such contracts only with counterparties the Adviser believes are creditworthy and by limiting the Fund's exposure to each counterparty. The Adviser will monitor the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis. The Sector Swaps will reference the individual sector indices that underlie the Primary Benchmark Index, which include S&P 500 Consumer Discretionary, S&P 500 Consumer Staples, S&P 500 Health Care, S&P 500 Industrials, S&P 500 Information Technology, S&P 500 Materials, S&P 500 Real Estate, S&P 500 Telecommunication Services, S&P 500 Utilities, S&P 500 Financials, and S&P 500 Energy (individually, ''Primary Benchmark Sector Index,'' and, collectively, ''Primary Benchmark Sector Indexes''). The Exchange notes that the Primary Benchmark Index and each Primary Benchmark Sector Index separately meet the generic listing standards applicable to Index Fund Shares under BZX Rule 14.11(c)(3)(A)(i).

[13] For purposes of this proposal, the term ETF includes Portfolio Depositary Receipts, Index Fund Shares, and Managed Fund Shares as defined in BZX Rules 14.11(b), (c), and (i), respectively, and their equivalents on other national securities exchanges.

[14] Such equity securities may include either component securities of the Primary Benchmark Index, ETFs based on the Primary Benchmark Index, or ETFs based on the sectors underlying the Primary Benchmark Index. Any such holdings will meet the listing requirements for U.S. Component Stocks as provided in BZX Rule 14.11(i)(4)(C)(i)(a).

[15] As defined in BZX Rule 14.11(i)(4)(C)(iii)(b), Cash Equivalents are short-term instruments with maturities of less than three months, which includes only the following: (i) U.S. Government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. Government agencies or instrumentalities; (ii) certificates of deposit issued against funds deposited in a bank or savings and loan association; (iii) bankers acceptances, which are short-term credit instruments used to finance commercial transactions; (iv) repurchase agreements and reverse repurchase agreements; (v) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (vi) commercial paper, which are short-term unsecured promissory notes; and (vii) money market funds.

[16] *See supra* note 10.

[17] All of the Fund's investments made pursuant to this second investment model will meet the listing requirements for U.S. equity securities as provided in BZX Rule 14.11(i)(4)(C)(i)(a).

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78k–1(a)(1)(C)(iii)

Fund's website includes a form of the prospectus for the Fund and additional information related to NAV and other applicable quantitative information. Information regarding market price and trading volume of the Shares will be continuously available throughout the day on brokers' computer screens and other electronic services. Quotation and last-sale information on the Shares will be available through the Consolidated Tape Association. Trading in the Shares may be halted for market conditions or for reasons that, in the view of the Exchange, make trading inadvisable. The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange represents that it has appropriate rules to facilitate trading in the Shares during all trading sessions.

The Commission notes that, in support of its proposal, the Exchange has made the following additional representations:

(1) As noted above, the Exchange represents that, apart from the exception to BZX Rule 14.11(i)(4)(C)(v) relating to holdings in OTC derivatives, the Fund will meet and be subject to all other requirements of the generic listing standards and other applicable continued listing requirements for Managed Fund Shares under BZX Rule 14.11(i), including those requirements regarding the Disclosed Portfolio and the requirement that the Disclosed Portfolio and the NAV will be made available to all market participants at the same time,[21] Intraday Indicative Value,[22] suspension of trading or removal,[23] trading halts,[24] disclosure,[25] and firewalls.[26]

(2) Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares. All of the equity securities held by the Fund will trade on markets that are a member of Intermarket Surveillance Group (''ISG'') or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange, the Financial Industry Regulatory Authority, Inc. (''FINRA''), on behalf of the Exchange, or both will communicate regarding trading in the Shares and the underlying equity securities held by the Fund with the ISG, other markets or entities who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. The Exchange, FINRA, on behalf of the Exchange, or both may obtain information regarding trading in the Shares and the underlying equity securities held by the Fund via the ISG from other markets or entities who are members or affiliates of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. Additionally, the Exchange or FINRA, on behalf of the Exchange, may access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine. The Exchange has a policy prohibiting the distribution of material non-public information by its employees.

(3) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (c) how information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (d) the risks involved in trading the Shares during the Pre-Opening [27] and After Hours Trading Sessions [28] when an updated Intraday Indicative Value and Underlying Index value will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information. In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act.

(4) The Fund's investments, including derivatives, will be consistent with the 1940 Act, and the Fund's investment objective and policies and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage).[29]

(5) The Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).

(6) The Fund will only use those derivatives included in the defined term ''Sector Swaps.'' The Fund's use of derivative instruments will be collateralized.

(7) The Trust is required to comply with Rule 10A–3 under the Act [30] for the initial and continued listing of the Shares of the Fund, and at least 100,000 Shares will be outstanding upon the commencement of trading.

(8) The Fund will attempt to limit counterparty risk in Sector Swaps by entering into such contracts only with counterparties the Adviser believes are creditworthy and by limiting the Fund's exposure to each counterparty. The Adviser will monitor the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis.

(9) All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values, and the applicability of Exchange rules specified in this filing shall constitute continued listing requirements for the Fund. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund or the Shares to comply with the continued listing requirements, and, pursuant to its

[21] *See* Rules 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[22] *See* Rule 14.11(i)(4)(B)(i).

[23] *See* Rule 14.11(i)(4)(B)(iii).

[24] *See* Rule 14.11(i)(4)(B)(iv).

[25] *See* Rule 14.11(i)(6).

[26] *See* Rule 14.11(i)(7).

[27] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[28] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[29] According to the Exchange, the Fund will include appropriate risk disclosure in its offering documents, including leveraging risk, which is the risk that certain transactions of a fund, including a fund's use of derivatives, may give rise to leverage, causing a fund to be more volatile than if it had not been leveraged. The Fund's investments in derivative instruments will be made in accordance with the 1940 Act and consistent with the Fund's investment objective and policies. To mitigate leveraging risk, the Fund will segregate or earmark liquid assets determined to be liquid by the Adviser in accordance with procedures established by the Trust's Board and in accordance with the 1940 Act (or, as permitted by applicable regulations, enter into certain offsetting positions) to cover its obligations under derivative instruments. These procedures have been adopted consistent with Section 18 of the 1940 Act and related Commission guidance.

[30] *See* 17 CFR 240.10A–3.

obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

This approval order is based on all of the Exchange's representations and description of the Shares and the Fund, including those set forth above and in Amendment Nos. 1 and 2 to the proposed rule change. Except as described herein, the Commission notes that the Shares must comply with all applicable requirements of BZX Rule 14.11(i) to be listed and traded on the Exchange on an initial and continuing basis.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with Section 6(b)(5) of the Act [31] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[32] that the proposed rule change (SR–CboeBZX–2017–076), as modified by Amendment Nos. 1 and 2, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26735 Filed 12–10–18; 8:45 am]

BILLING CODE 8011–01–P

[31] 15 U.S.C. 78f(b)(5).

[32] 15 U.S.C. 78s(b)(2).

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84723; File No. SR–NASDAQ–2018–097]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay a New Protocol "Ouch to Trade Options" or "OTTO" on The Nasdaq Options Market LLC ("NOM")

December 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 26, 2018, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to a proposal to delay a new protocol "Ouch to Trade Options" or "OTTO" on The Nasdaq Options Market LLC ("NOM").

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq recently filed a rule change [3] which adopted a new protocol "Ouch to Trade Options" or "OTTO" [4] and renamed and modified the current OTTO protocol as "Quote Using Orders" or "QUO".[5] The Prior Rule Change, which is effective but not yet operative, renamed and modified the current OTTO protocol to "QUO." The Exchange subsequently filed a rule change to amend Chapter VI, Section 6(e), titled "Detection of Loss of Communication" which describes the impact to NOM protocols in the event of a loss of a communication. The Exchange accounted for both the new OTTO and renamed and modified QUO within this rule. Similarly, the Exchange amended Chapter VI, Section 8, "Nasdaq Opening and Halt Cross" to account for the new OTTO and renamed and modified QUO within this rule. Finally, the Exchange amended Chapter VI, Section 19, "Data Feeds and Trade Information" to amend "OTTO DROP" to "QUO DROP" and noted within Chapter VI, Section 18(a)(1) related to Order Price Protection rule or "OPP" that OPP shall not apply to orders entered through QUO.[6]

Both the Prior Rule Change and the Subsequent Rule Change indicated the aforementioned rule changes would be implemented for QUO and OTTO in Q4 of 2018 with the date announced via an Options Traders Alert. At this time, the Exchange proposes to immediately implement QUO and delay the introduction of new OTTO functionality until Q1 2019 by announcing the date of implementation via an Options Traders Alert. The Exchange proposes to provide for the delay of the OTTO functionality by inserting the following rule text at the beginning of NOM Rules at Chapter VI, Sections 6, 9 and 21 to make clear that OTTO functionality is not yet implemented: "OTTO functionality implementation shall be delayed until Q1 2019. The Exchange will issue an Options Trader Alert notifying Participants when this functionality will be available."

The Exchange proposes this delay to allow the Exchange additional time to implement this functionality and for

[3] *See* Securities Exchange Act Release No. 83888 (August 20, 2018), 83 FR 42954 (August 24, 2018) (SR–NASDAQ–2018–069) ("Prior Rule Change"). This rule change is immediately effective but will not be operative until such time as the Exchange issues an Options Trader Alert announcing the implementation date. This notification will be issued in Q4 2018. The Exchange notes that this filing renamed and modified the current OTTO protocol as "QUO" and also proposed the adoption of a new OTTO protocol.

[4] New OTTO is an interface that allows Participants and their Sponsored Customers to connect, send, and receive messages related to orders to and from the Exchange. Features include the following: (1) Options symbol directory messages (*e.g.,* underlying); (2) system event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) order messages; and (6) risk protection triggers and cancel notifications. *See* NOM Rules at Chapter VI, Section 21(a)(i)(C).

[5] QUO is an interface that allows NOM Market Makers to connect, send, and receive messages related to single-sided orders to and from the Exchange. Order Features include the following: (1) Options symbol directory messages (*e.g.,* underlying); (2) system event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) order messages; and (6) risk protection triggers and cancel notifications. Orders submitted by NOM Market Makers over this interface are treated as quotes. *See* NOM Rules at Chapter VI, Section 21(a)(i)(D).

[6] *See* Securities Exchange Act Release No. 84559 (November 9, 2019), 83 FR 57774 (November 16, 2018) (SR–NASDAQ–2018–085) ("Subsequent Rule Change").

Participants to sign-up for this new port and test with the Exchange.

Amend OTTO at Options 7

The Exchange's current pricing at Options 7,[7] Section 3(i)(4) reflects an OTTO Port Fee. The Exchange proposed to rename the OTTO Port Fee as ''QUO Port Fee'' to reflect the new name of the modified former OTTO protocol. No changes are being made to the port fee. Likewise, the current ''OTTO DROP Port Fee'' at Options 7, Section 3(ii)(4) is proposed to be renamed the ''QUO DROP Port Fee.''

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, 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 delaying the OTTO functionality to allow the Exchange additional time to implement this functionality and for Participants to sign-up for this new port and test with the Exchange. QUO would be implemented to avoid any confusion with the new proposed protocol.

QUO

The Exchange's proposal to rename the current ''OTTO Port Fee'' as ''QUO Port Fee'' and ''OTTO DROP Port Fee'' as ''QUO DROP Port Fee'' is consistent with the Act because the amendment will reflect the name change and modification as proposed in the Prior Rule Change.

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 implement QUO and delay the adoption of new OTTO functionality does not impose an undue burden on competition. Immediately implementing the QUO protocol, which is the subject of an already effective rule change, will avoid any confusion with the implementation of the new OTTO protocol. Delaying the new OTTO functionality to allow the Exchange additional time to implement this functionality and for Participants to sign-up for this new port and test with the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) [12] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [13] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the waiver will allow the Exchange to immediately implement QUO and delay the implementation of the OTTO functionality to allow the Exchange additional time to implement this functionality and for Participants to sign-up for this new port and test with the Exchange. The Exchange further states that delaying the implementation of OTTO is consistent with the protection of investors and the public interest because it permits additional time for the Exchange to ensure a successful implementation of new OTTO. Additionally, the Exchange notes that implementing QUO will bring greater transparency to NOM rules. 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 as operative upon filing.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2018–097 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–2018–097. 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

[7] Options 7 refers to the Exchange's new rulebook shell.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 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 the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–2018–097 and should be submitted on or before January 2, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26736 Filed 12–10–18; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15746 and #15747; North Carolina Disaster Number NC–00100]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Carolina (FEMA–4393–DR), dated 10/12/2018.

Incident: Hurricane Florence.

Incident Period: 09/07/2018 through 09/29/2018.

DATES: Issued on 11/15/2018.

Physical Loan Application Deadline Date: 12/11/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 07/12/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of North Carolina, dated 10/12/2018, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Guilford, McDowell.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26711 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15748 and #15749; Virginia Disaster Number VA–00075]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the Commonwealth of Virginia

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Virginia (FEMA–4401–DR), dated 10/15/2018.

Incident: Hurricane Florence.

Incident Period: 09/08/2018 through 09/21/2018.

DATES: Issued on 11/14/2018.

Physical Loan Application Deadline Date: 12/14/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 07/15/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Virginia, dated 10/15/2018, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Craig, Floyd, Grayson, Isle of Wight, and the independent city of Hampton.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26710 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15780 and #15781; Florida Disaster Number FL–00141]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Florida (FEMA–4399–DR), dated 10/23/2018.

Incident: Hurricane Michael.

Incident Period: 10/07/2018 through 10/19/2018.

DATES: Issued on 11/15/2018.

Physical Loan Application Deadline Date: 12/24/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 07/23/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Florida, dated 10/23/2018, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Franklin, Holmes, Jefferson, Leon, Madison, Okaloosa, Taylor, Wakulla, Walton, Washington.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26715 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15782 and #15783; Northern Mariana Islands Disaster Number MP–00009]

Presidential Declaration Amendment of a Major Disaster for the Commonwealth of the Northern Mariana Islands

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the Commonwealth of the Northern Mariana Islands (FEMA–4404–DR), dated 10/26/2018.

Incident: Super Typhoon Yutu.

Incident Period: 10/24/2018 through 10/26/2018.

DATES: Issued on 11/10/2018.

Physical Loan Application Deadline Date: 01/27/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 07/26/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for the Commonwealth of the Northern Mariana Islands, dated 10/26/2018, is hereby amended to extend the deadline for filing applications for physical damages as a result of this disaster to 01/27/2019.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26716 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15798 and #15799; California Disaster Number CA–00295]

Presidential Declaration of a Major Disaster for the State of California

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of California (FEMA–4407–DR), dated 11/12/2018.

Incident: Wildfires.

Incident Period: 11/08/2018 and continuing.

DATES: Issued on 11/12/2018.

Physical Loan Application Deadline Date: 01/11/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 08/12/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/12/2018, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Butte, Los Angeles, Ventura

Contiguous Counties (Economic Injury Loans Only):

California: Colusa, Glenn, Kern, Orange, Plumas, San Bernardino, Santa Barbara, Sutter, Tehama, Yuba

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	4.000
Homeowners without Credit Available Elsewhere	2.000
Businesses with Credit Available Elsewhere	7.480
Businesses without Credit Available Elsewhere	3.740
Non-Profit Organizations with Credit Available Elsewhere	2.750
Non-Profit Organizations without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.740
Non-Profit Organizations without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 157985 and for economic injury is 157990.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26717 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 07/07–0122]

Eagle Fund IV–A, L.P.; Notice Seeking Exemption Under the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Eagle Fund IV–A, L.P., 1 North Brentwood Blvd., Suite 1550, St. Louis, MO 63105, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Eagle Fund IV–A, L.P. is seeking a prior written exemption from SBA for loan and equity financings it made to RHI Acquisition, LLC, 2 Oliver Street, Boston, MA 02109.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Eagle Fund III, L.P., and Eagle Fund III–A, L.P., (collectively ''Eagle III'') Associates of Eagle Fund IV–A, L.P., own more than ten percent of RHI Acquisition, LLC, and therefore this transaction is considered *Financing an Associate* requiring prior SBA written exemption. Eagle Fund IV–A, L.P., has not made its investment in RHI Acquisition, LLC and is seeking pre-financing SBA approval.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

A. Joseph Shepard,

Associate Administrator for Office of Investment and Innovation.

[FR Doc. 2018–26792 Filed 12–10–18; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[License No. 07/07–0121]

Eagle Fund IV, L.P.; Notice Seeking Exemption Under the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Eagle Fund IV, L.P., 1 North Brentwood Blvd., Suite 1550, St. Louis, MO 63105, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). Eagle Fund IV, L.P. is seeking approval prior written exemption from SBA for loan and equity financings it made to RHI Acquisition, LLC, 2 Oliver Street, Boston, MA 02109.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Eagle Fund III, L.P., and Eagle Fund III–A, L.P., (collectively ''Eagle III'') Associates of Eagle Fund IV, L.P., own more than ten percent of RHI Acquisition, LLC, and therefore this transaction is considered *Financing an Associate* requiring prior SBA written exemption. Eagle Fund IV, L.P., has not made its investment in RHI Acquisition, LLC and is seeking pre-financing SBA approval.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

A. Joseph Shepard,

Associate Administrator for Office of Investment and Innovation.

[FR Doc. 2018–26791 Filed 12–10–18; 8:45 am]

BILLING CODE P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15804 and #15805; Pennsylvania Disaster Number PA–00094]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Commonwealth of Pennsylvania

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Pennsylvania (FEMA–4408–DR), dated 11/27/2018.

Incident: Severe Storms and Flooding.

Incident Period: 08/10/2018 through 08/15/2018.

DATES: Issued on 11/27/2018.

Physical Loan Application Deadline Date: 01/28/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 08/27/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/27/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Bradford, Columbia, Lackawanna, Lycoming, Montour, Schuylkill, Sullivan, Susquehanna, Tioga, Wyoming.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 158046 and for economic injury is 158050.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26707 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15825 and #15826; Tohono O'odham Nation Disaster Number AZ–00058]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Tohono O'Odham Nation

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Tohono O'odham Nation (FEMA–4409–DR), dated 11/30/2018.

Incident: Severe Storms and Flooding.

Incident Period: 10/01/2018 through 10/03/2018.

DATES: Issued on 11/30/2018.

Physical Loan Application Deadline Date: 01/29/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 08/30/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 11/30/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Tohono O'odham Nation

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.500
Non-Profit Organizations without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 158256 and for economic injury is 158260.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26705 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15788 and #15789; Georgia Disaster Number GA–00109]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Georgia

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Georgia (FEMA–4400–DR), dated 11/01/2018.

Incident: Hurricane Michael.

Incident Period: 10/09/2018 through 10/23/2018.

DATES: Issued on 11/15/2018.

Physical Loan Application Deadline Date: 12/31/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 08/02/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Georgia, dated 11/01/2018, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Hancock, Tattnall.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2018–26706 Filed 12–10–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 10577]

60-Day Notice of Proposed Information Collection: Special Immigrant Visa Form

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to February 11, 2019.

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

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering ''Docket Number: DOS–2018–0049'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: JonesJI2@state.gov.*
- *Regular Mail:* Send written comments to: Irving Jones, PRM/Admissions, 2025 E Street NW, SA–9, 8th Floor, Washington, DC 20522–0908.
- *Fax:* 202–453–9393.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Irving Jones, PRM/Admissions, 2025 E Street NW, SA–9, 8th Floor, Washington, DC 20522–0908, who may be reached on 202–453–9248 or at *JonesJI2@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Special Immigrant Visa Biodata Form.
- *OMB Control Number:* 1405–0203.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Office of Admissions, Bureau of Population, Refugees and Migration (PRM/A).
- *Form Number:* DS–0234.
- *Respondents:* Iraqi and Afghan Special Immigrant Visa Applicants.
- *Estimated Number of Respondents:* 14,000.
- *Estimated Number of Responses:* 14,000.
- *Average Time per Response:* 15 minutes.
- *Total Estimated Burden Time:* 3,500 Annual hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Form DS–234 is being added to this collection to elicit information used to determine the eligibility of Iraqis and Afghan nationals applying for special immigrant visas.

Methodology

The SIV Biodata information form (DS–234) is submitted electronically by the applicant to the National Visa Center, which will forward the forms to the Refugee Processing Center of the Bureau of Population, Refugees and Migration.

Kelly Gauger,

Acting Office Director, Bureau of Population, Refugees, and Migration, Department of State.

[FR Doc. 2018–26696 Filed 12–10–18; 8:45 am]

BILLING CODE 4710–33–P

SURFACE TRANSPORTATION BOARD

[STB Docket No. AB 1271X]

Savage, Bingham & Garfield Railroad Company—Discontinuance of Trackage Rights Exemption—in Whiting, Ind.

On November 21, 2018, Savage, Bingham & Garfield Railroad Company

(SBG) filed a petition [1] under 49 U.S.C. 10502 to (1) revoke the exemption that authorized SBG to operate pursuant to a trackage rights agreement entered into between SBG and Elgin, Joliet and Eastern Railway Company (CN),[2] over a 0.6-mile rail line owned by CN in Whiting, Ind. (the Line) and (2) allow the trackage rights to terminate. The Line is located between milepost J 47.4 (south end of CN's Whiting Line) and Bridge Number 631 at or near milepost J 46.8 on CN's Calumet Spur on CN's Matteson Subdivision in Whiting, Ind.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by March 11, 2019.

Because this is a discontinuance proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Similarly, no environmental or historic documentation is required under 49 CFR 1105.6(c)(5) and 1105.8(b)(3).

Any offer of financial assistance (OFA) for subsidy under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner.[3] Each OFA must be accompanied by the filing fee, which is currently set at $1,800. *See* 49 CFR 1002.2(f)(25).

All filings in response to this notice must refer to STB Docket No. AB 1271X and must be sent to: (1) Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001 and (2) Richard F. Riley Jr., Foley & Lardner LLP, 3000 K Street NW, Suite 600, Washington, DC 20007–5109. Replies to the petition are due on or before December 31, 2018.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment and discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Board decisions and notices are available on our website at *www.stb.gov*.

Decided: December 6, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–26807 Filed 12–10–18; 8:45 am]

BILLING CODE 4915–01–P

[1] SBG's petition is styled as a petition to revoke. However, petitions to revoke trackage rights agreements typically are appropriate when filed concurrently with a trackage rights verified notice of exemption. *See, e.g., Union Pac. R.R.—Trackage Rights Exemption—Burlington N. & Santa Fe Ry.,* FD 33631 (Sub-No. 1), slip op. at 2 (STB served July 30, 1998) (''We see nothing objectionable with this procedure when, as here, the petition and notice are filed together.''). Here, the appropriate procedure is a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to discontinue SBG's trackage rights over the Line.

[2] Elgin, Joliet and Eastern Railway Company is an indirect subsidiary of Canadian National Railway Company.

[3] The Board modified its OFA procedures effective July 29, 2017. Among other things, the OFA process now requires potential offerors in all abandonment and discontinuance proceedings to file a formal expression of intent to file an offer. The process also requires potential offerors, in their formal expression of intent, to make a preliminary financial responsibility showing based on a calculation using information contained in the carrier's filing and publicly-available information. *See Offers of Financial Assistance,* EP 729 (STB served June 29, 2017); 82 FR 30997 (July 5, 2017).

SURFACE TRANSPORTATION BOARD

[Docket No. EP 730 (Sub–No. 1)]

Roster of Arbitrators—Annual Update

Under Section 13 of the Surface Transportation Board Reauthorization Act of 2015 (STB Reauthorization Act), codified at 49 U.S.C. 11708, Congress directed the Board to ''promulgate regulations to establish a voluntary and binding arbitration process to resolve rail rate and practice complaints'' that are subject to the Board's jurisdiction. In May 2016, the Board issued a Notice of Proposed Rulemaking proposing to modify its existing regulations at 49 CFR 1108 and 1115.8 to conform to the requirements of the STB Reauthorization Act. *Revisions to Arbitration Procedures,* EP 730 (STB served May 12, 2016). Section 11708(f) provides that, unless parties otherwise agree, an arbitrator or panel of arbitrators shall be selected from a roster maintained by the Board. Accordingly, the Board's rules establish a process for creating and maintaining a roster of arbitrators. *See Revisions to Arbitration Procedures* (*Final Rule*), EP 730, slip op. at 3–4 (STB served Oct. 11, 2016).

By decision served February 23, 2017, the Board adopted its initial roster of arbitrators and updated the roster by decision served February 14, 2018. The roster is published on the Board's website at *https://www.stb.gov/stb/litigationalternatives/CurrentArbitration.html* (under ''Arbitration Procedures'').

Under 49 CFR 1108.6(b), the Board is to update the roster of arbitrators annually. Accordingly, the Board is now requesting the names and qualifications of new arbitrators who wish to be placed on the roster. Current arbitrators who wish to remain on the roster must notify the Board of their continued availability and confirm that the biographical information on file with the Board remains accurate and if not, provide any necessary updates. Arbitrators who do not confirm their continued availability will be removed from the roster. This decision will be served on all current arbitrators.

Any person who wishes to be added to the roster should file an application describing his or her experience with rail transportation and economic regulation, as well as professional or business experience, including agriculture, in the private sector. Each applicant should also describe his or her training in dispute resolution and/or experience in arbitration or other forms of dispute resolution, including the number of years of experience. Lastly, the applicant should provide his or her contact information and fees.

All comments—including filings from new applicants, updates to existing arbitrator information, and confirmations of continued availability—should be submitted by January 11, 2019.[1] The Board will assess each new applicant's qualifications to determine which individuals can ably serve as arbitrators based on the criteria established under 49 CFR 1108.6(b). The Board will then establish an updated roster of arbitrators by no-objection vote. The roster will include a brief biographical sketch of each arbitrator, including information such as background, area(s) of expertise, arbitration experience, and geographical location, as well as contact information and fees. The roster will be published on the Board's website.

It is ordered:

1. Applications from persons interested in being added to the Board's roster of arbitrators, and confirmations of continued availability (with updates, if any, to existing arbitrator information) from persons currently on the arbitration roster, are due by January 11, 2019.

2. This decision will be served on all current arbitrators and published in the **Federal Register**.

[1] Persons who have informally indicated an interest in being included on the arbitrator roster (*e.g.,* correspondence to Board members) should submit a comment pursuant to this decision.

3. This decision is effective on the date of service.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–26785 Filed 12–10–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans, that are final. The actions relate to the Mount Vernon Avenue Bridge Project, which would replace the existing Mount Vernon Avenue Bridge (Bridge Number 54C–066) over the Burlington Northern Santa Fe (BNSF) rail yard in the City of San Bernardino, San Bernardino County, California. Those actions grant approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the Off the Highway System Project will be barred unless the claim is filed on or BEFORE May 10, 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 applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Aaron Burton, Senior Environmental Planner, Local Assistance-Environmental Support, California Department of Transportation District 8, 464 West Fourth Street, 6th floor, MS 760, San Bernardino, CA 92401 during regular office hours from 8:00 a.m. to 5:00 p.m., Telephone number: (909) 383–2841, email: *aaron.burton@dot.ca.gov.* For FHWA, contact Larry Vinzant at (916) 498–5040 or email *larry.vinzant@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following Mount Vernon Avenue Bridge Project in the State of California. The Mount Vernon Avenue Bridge Project proposes to replace the existing Mount Vernon Avenue Bridge (Bridge Number 54C–066) over the BNSF rail yard in the City of San Bernardino, San Bernardino County, California. The proposed project covers a distance of approximately 0.5 mile. The purpose of the project is to provide a bridge that is structurally safe and meets current seismic, design, and roadway standards. A National Environmental Policy Act (NEPA) Finding of No Significant Impact (FONSI) was adopted for the project in June 2011. Since the NEPA document was adopted, it has been noted that additional project improvements and refinements are needed that were not included in the adopted NEPA document. A Supplemental Environmental Assessment (EA) was prepared to focus on impacts that would result from proposed changes to the approved project since adoption of the FONSI in 2011.

Mount Vernon Avenue is considered a Major Arterial per the City of San Bernardino General Plan. Thus, it is a connecting link between economic centers both within the City and the region as a whole. Mount Vernon Avenue Bridge provides an additional access route to rail and mass transit (Metrolink) facilities in the immediate area that also interface with port and airport facilities. The bridge is currently closed to all commercial traffic, including trucks and buses. Any permanent long-term closure of the Mount Vernon Avenue Bridge would remove an important connection linking communities north and south of the BNSF railroad. Implementation of the Mount Vernon Avenue Bridge Project would replace the existing bridge to improve seismic performance, provide standard vertical clearance over the rail tracks, and comply with American Association of State Highway and Transportation Officials (AASHTO) roadway cross section standards.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Supplemental EA for the project, approved on May 22, 2018 and the FONSI issued on October 9, 2018 and in other documents in the Caltrans' project records. The EA, FONSI and other project records are available by contacting Caltrans at the address provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project website at *http://gosbcta.com/plans-projects/projects/mt-vernon/envi-docs/2018-eval/Mt_Vernon_EA_Final_52218.pdf.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].

2. Clean Air Act [42 U.S.C. 7401–7671(q)].

3. Section 4(f) of the U.S. Department of Transportation Act of 1966 [49 U.S.C. 303].

4. Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [16 U.S.C. 469 469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. Clean Water Act 33 U.S.C. 1251–1387.

7. Farmland Protection Policy Act [7 U.S.C. 4201–4209 and its regulations].

8. E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Shawn Oliver,

Environmental Team Leader, Federal Highway Administration, Sacramento, California.

[FR Doc. 2018–26759 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, the U.S. Highway 101 Managed Lanes Project from post miles 50.6 in Santa Clara County to 21.8 in San Mateo County, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before May 10, 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 applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Yolanda Rivas, Environmental Branch Chief, 111 Grand Avenue MS 8B, Oakland, CA 94612, 510–286–6216 (Voice), email *yolanda.rivas@dot.ca.gov.* For FHWA, contact Larry Vinzant at (916) 498–5040 or email *larry.vinzant@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and Caltrans assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals. The U.S. Highway 101 Managed Lanes Project proposes to provide continuous managed lanes in the northbound and southbound directions of US 101 in Santa Clara and San Mateo counties from the terminus of the existing high-occupancy vehicle (HOV) lanes in northern Santa Clara County to north of Interstate 380. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the project, approved on November 30, 2018. The EA, FONSI, and other project records are available by contacting Caltrans at the address provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project website at *http://www.dot.ca.gov/d4/101managedlanes/.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act (NEPA)
2. Fixing America's Surface Transportation Act (Fast Act)
3. Clean Air Act
4. Federal-Aid Highway Act
5. Clean Water Act
6. Historic Sites Act
7. Section 106 of the National Historic Preservation Act
8. Archeological Resources Protection Act
9. Archeological and Historic Preservation Act
10. Antiquities Act
11. Endangered Species Act
12. Migratory Bird Treaty Act
13. Fish and Wildlife Coordination Act
14. Magnuson-Stevens Fishery Conservation and Management Act
15. Section 4(f) of the Department of Transportation Act
16. Civil Rights Act, Title VI
17. Farmland Protection Policy Act
18. Uniform Relocation Assistance and Real Property Acquisition Policies Act
19. Rehabilitation Act
20. Americans With Disabilities Act
21. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
22. Resource Conservation and Recovery Act (RCRA)
23. Safe Drinking Water Act
24. Occupational Safety and Health Act
25. Atomic Energy Act
26. Toxic Substances Control Act
27. Federal Insecticide, Fungicide and Rodenticide Act
28. E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management
29. E.O. 12898, Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations
30. E.O. 12088, Federal Compliance With Pollution Control Standards

(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).

Tashia J. Clemons,

Director, Planning and Environment, Federal Highway Administration, Sacramento, California.

[FR Doc. 2018–26758 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT–MARAD–2018–0179]

Request for Comments on the Renewal of a Previously Approved Information Collection: Application for Conveyance of Port Facility Property

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information collection is necessary for MARAD to determine whether the applicant is committed to the redevelopment plan; the plan is in the best interests of the public, and the property will be used in accordance with the terms of the conveyance and applicable statutes and regulations. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before February 11, 2019.

ADDRESSES: You may submit comments [identified by Docket No. DOT–MARAD–2018–0179 through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Linden Houston, Office of Deepwater Ports and Offshore Activities, Maritime Administration, 1200 New Jersey Avenue SE, Washington, DC 20590;

Telephone: (202) 366–4839 or email: mailto:*Linden.Houston@dot.gov*. Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title: Application for Conveyance of Port Facility Property.

OMB Control Number: 2133–0524.

Type of Request: Renewal of a Previously Approved Information Collection.

Abstract: Public Law 103–160, which is included in 40 U.S.C. 554 authorizes the Department of Transportation to convey to public entities surplus Federal property needed for the development or operation of a port facility. The information collection will allow MARAD to approve the conveyance of property and administer the port facility conveyance program.

Respondents: Eligible state and local public entities.

Affected Public: Eligible state and local public entities.

Estimated Number of Respondents: 13.

Estimated Number of Responses: 13.

Estimated Hours per Response: 44.

Annual Estimated Total Annual Burden Hours: 572.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.93.) * * *

Dated: December 4, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26723 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket ID PHMSA–2018–0103]

Pipeline Safety: Random Drug Testing Rate; Management Information System Reporting; and Obtaining Drug and Alcohol Management Information System Sign-In Information

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of Calendar Year 2019 Minimum Annual Percentage Rate for Random Drug Testing, Reminder for Operators to Report Contractor MIS Data, and Reminder of Method for Operators to Obtain User Name and Password for Electronic Reporting.

SUMMARY: PHMSA has determined that the minimum random drug testing rate for covered employees will remain at 50 percent during calendar year 2019. Operators are reminded that drug and alcohol testing information must be submitted for contractors who are performing or are ready to perform covered functions. For calendar year 2018 reporting, the ''user name'' and ''password'' for the Drug and Alcohol Management Information System (DAMIS) will be available in the PHMSA Portal.

DATES: Effective January 1, 2019, through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Wayne Lemoi, Drug & Alcohol Program Manager, telephone at 909–937–7232 or by email at *wayne.lemoi@dot.gov*.

SUPPLEMENTARY INFORMATION:

Notice of Calendar Year 2019 Minimum Annual Percentage Rate for Random Drug Testing

Operators of natural gas, hazardous liquid, and carbon dioxide pipelines and operators of liquefied natural gas and underground natural gas storage facilities must randomly select and test a percentage of all covered employees for prohibited drug use in accordance with 49 CFR part 199. Pursuant to § 199.105(c)(1), the PHMSA minimum annual random drug testing rate for all covered employees is 50 percent. The Administrator can adjust this random drug testing rate based on the reported positive rate in the pipeline industry's random drug tests, which is submitted in operators' annual Management Information System (MIS) reports as required by § 199.119(a). In accordance with § 199.105(c)(3), if the reported positive drug test rate is below 1 percent for 2 consecutive years, the Administrator can reduce the random drug testing rate to 25 percent of all covered employees. In calendar year 2017, the random drug test positive rate for the entire pipeline industry was reported at greater than 1 percent; therefore, the minimum annual random drug testing rate for calendar year 2019 is maintained at 50 percent of all covered employees.

Reminder for Operators To Report Contractor MIS Data

On January 19, 2010, (75 FR 2926) PHMSA published an advisory bulletin notifying operators of the appropriate methodology for the annual collection of contractor MIS drug and alcohol testing data to avoid duplicative reporting when a contractor works for multiple operators. If an operator is required to submit a MIS report in accordance with part 199, that report is not complete until PHMSA receives MIS data for each tested contractor that performed covered functions as defined in § 199.3. As explained in the 2010 Advisory Bulletin, operators must submit operator and contractor employee testing data in separate MIS reports to avoid duplicative reporting and inaccurate data that could affect the positive rate for the entire industry.

Reminder of Method for Operators To Obtain User Name and Password for Electronic Reporting

By early January 2019, the user name and password required for an operator to access DAMIS and enter calendar year 2018 data will be available to all operator staff with access to the PHMSA Portal. Pipeline operators have been submitting reports required by 49 CFR parts 191 and 195 through the PHMSA Portal (*https://portal.phmsa.dot.gov/pipeline*) since 2011. PHMSA determined that distributing information via the Portal would be more effective than the previous mailing process.

When the DAMIS user name and password are available in the PHMSA Portal, all registered users will receive an email to that effect. If operator staff responsible for submitting MIS reports do not receive the DAMIS information, they should coordinate with other registered PHMSA Portal users within their company to obtain the DAMIS user name and password. Registered PHMSA Portal users for an operator typically include operator staff or consultants who submit annual and incident reports through PHMSA F 7000- and 7100-series forms. Operators that have not previously registered staff in the PHMSA Portal for the reporting purposes of parts 191 and 195 can register users by following the instructions at: *https://portal.phmsa.dot.gov/PHMSAPortal2/staticContentRedesign/howto/PortalAccountCreation.pdf*.

Pursuant to §§ 199.119(a) and 199.229(a), operators with 50 or more covered employees, including both operator and contractor staff, are required to submit annual MIS reports. Operators with fewer than 50 total covered employees are required to submit MIS reports only upon written request from PHMSA. If an operator with fewer than 50 total covered employees has submitted an MIS report in or after calendar year 2016, the PHMSA Portal message may state that no MIS report is required for calendar year 2018. If an operator with fewer than 50 covered employees has grown to more than 50 covered employees during calendar year 2018, the PHMSA Portal message will include instructions for

how to obtain a DAMIS user name and password for the 2018 calendar year reporting period.

Issued in Washington, DC, on December 3, 2018, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2018–26750 Filed 12–10–18; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF VETERANS AFFAIRS

National Research Advisory Council; Notice of Meeting; Cancellation

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the meeting of the National Research Advisory Council previously scheduled to be held on Wednesday, December 5, 2018, at 1100 First Street NE, Room 104, Washington, DC 20002, *has been cancelled.*

For more information, please contact Ms. Rashelle Robinson, Designated Federal Officer at (202) 443–5668, or via email at *Rashelle.Robinson@va.gov.*

Dated: December 4, 2018.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–26714 Filed 12–10–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 83 Tuesday,
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Part II

Environmental Protection Agency

40 CFR Part 80
Renewable Fuel Standard Program: Standards for 2019 and Biomass-Based Diesel Volume for 2020; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[EPA–HQ–OAR–2018–0167; FRL–9987–66–OAR]

RIN 2060–AT93

Renewable Fuel Standard Program: Standards for 2019 and Biomass-Based Diesel Volume for 2020

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Under section 211 of the Clean Air Act, the Environmental Protection Agency (EPA) is required to set renewable fuel percentage standards every year. This action establishes the annual percentage standards for cellulosic biofuel, biomass-based diesel, advanced biofuel, and total renewable fuel that apply to gasoline and diesel transportation fuel produced or imported in the year 2019. Relying on statutory waiver authority that is available when the projected cellulosic biofuel production volume is less than the applicable volume specified in the statute, EPA is establishing volume requirements for cellulosic biofuel, advanced biofuel, and total renewable fuel that are below the statutory volume targets. We are also establishing the applicable volume of biomass-based diesel for 2020.

DATES: This final rule is effective on February 11, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2018–0167. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material is not available on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Julia MacAllister, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4131; email address: *macallister.julia@epa.gov.*

SUPPLEMENTARY INFORMATION: Entities potentially affected by this final rule are those involved with the production, distribution, and sale of transportation fuels, including gasoline and diesel fuel or renewable fuels such as ethanol, biodiesel, renewable diesel, and biogas. Potentially affected categories include:

Category	NAICS [1] codes	SIC [2] codes	Examples of potentially affected entities
Industry	324110	2911	Petroleum refineries.
Industry	325193	2869	Ethyl alcohol manufacturing.
Industry	325199	2869	Other basic organic chemical manufacturing.
Industry	424690	5169	Chemical and allied products merchant wholesalers.
Industry	424710	5171	Petroleum bulk stations and terminals.
Industry	424720	5172	Petroleum and petroleum products merchant wholesalers.
Industry	221210	4925	Manufactured gas production and distribution.
Industry	454319	5989	Other fuel dealers.

[1] North American Industry Classification System (NAICS).
[2] Standard Industrial Classification (SIC).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your entity would be affected by this action, you should carefully examine the applicability criteria in 40 CFR part 80. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Outline of This Preamble

I. Executive Summary

The Renewable Fuel Standard (RFS) program began in 2006 pursuant to the requirements in Clean Air Act (CAA) section 211(o) that were added through the Energy Policy Act of 2005. The statutory requirements for the RFS program were subsequently modified through the Energy Independence and Security Act of 2007 (EISA), leading to the publication of major revisions to the regulatory requirements on March 26, 2010.[1] EISA's stated goals include moving the United States (U.S.) toward ''greater energy independence and security [and] increase[ing] the production of clean renewable fuels.'' [2]

The statute includes annual volume targets, and requires EPA to translate those volume targets (or alternative volume requirements established by EPA in accordance with statutory waiver authorities) into compliance obligations that obligated parties must meet every year. In this action we are finalizing the applicable volumes for cellulosic biofuel, advanced biofuel, and total renewable fuel for 2019, and biomass-based diesel (BBD) for 2020.[3] We are also finalizing the annual percentage standards (also known as ''percent standards'') for cellulosic biofuel, BBD, advanced biofuel, and total renewable fuel that would apply to all gasoline and diesel produced or imported in 2019.[4]

Today, nearly all gasoline used for transportation purposes contains 10 percent ethanol (E10), and on average diesel fuel contains nearly 5 percent biodiesel and/or renewable diesel.[5] However, the market has fallen well short of the statutory volumes for cellulosic biofuel, resulting in shortfalls in the advanced biofuel and total renewable fuel volumes. In this action, we are finalizing a volume requirement for cellulosic biofuel at the level we project to be available for 2019, along with an associated applicable percentage standard. For advanced biofuel and total renewable fuel, we are finalizing reductions under the ''cellulosic waiver authority'' that would result in advanced biofuel and total renewable fuel volume requirements that are lower than the statutory targets by the same magnitude as the reduction in the cellulosic biofuel reduction. This would effectively maintain the implied statutory volumes for non-cellulosic advanced biofuel and conventional biofuel.[6]

The resulting final volume requirements for 2019 are shown in Table I–1 below. Relative to the levels finalized for 2018, the 2019 volume requirements for advanced biofuel and total renewable fuel would be higher by 630 million gallons. Approximately 130 million gallons of this increase would be due to the increase in the projected production of cellulosic biofuel in 2019 relative to 2018. The cellulosic biofuel volume is 37 million gallons greater than the proposed cellulosic biofuel volume for 2019. The advanced biofuel and total renewable fuel volumes are each 40 million gallons higher than the proposed volumes, as a result of an increased projection of cellulosic biofuel production in 2019 (see Section III for a further discussion of our cellulosic biofuel projection). We are also establishing the volume requirement for BBD for 2020 at 2.43 billion gallons. This volume is 330 million gallons higher than the volume for 2019.

TABLE I–1—FINAL VOLUME REQUIREMENTS [a]

	2018 [b]	2019 Statutory volumes	2019 Proposed volumes	2019 Final volumes	2020 Final volumes
Cellulosic biofuel (million gallons)	288	8,500	381	418	n/a
Biomass-based diesel (billion gallons)	2.1	≥1.0	N/A	[c] 2.1	[d] 2.43
Advanced biofuel (billion gallons)	4.29	13.00	4.88	4.92	n/a
Renewable fuel (billion gallons)	19.29	28.00	19.88	19.92	n/a

[a] All values are ethanol-equivalent on an energy content basis, except for BBD which is biodiesel-equivalent.
[b] The 2018 volume requirements for cellulosic biofuel, advanced biofuel, and renewable fuel were established in the 2018 final rule (82 FR 58486, December 12, 2017). The 2018 BBD volume requirement was established in the 2017 final rule (81 FR 89746, December 12, 2016).
[c] The 2019 BBD volume requirement was established in the 2018 final rule (82 FR 58486, December 12, 2017).
[d] EPA proposed 2.43 billion gallons of BBD in 2020 in the 2019 NPRM.

A. Summary of Major Provisions in This Action

This section briefly summarizes the major provisions of this final rule. We are finalizing applicable volume requirements and associated percentage standards for cellulosic biofuel, advanced biofuel, and total renewable fuel for 2019; for BBD we are finalizing the percentage standard for 2019 and the applicable volume requirement for 2020.

[1] 75 FR 14670, March 26, 2010.

[2] Public Law 110–140, 121 Stat. 1492 (2007). Hereinafter, ''EISA.''

[3] The 2019 BBD volume requirement was established in the 2018 final rule.

[4] For a list of the statutory provisions for the determination of applicable volumes, see the 2018 final rule (82 FR 58486, December 12, 2017; Table I.A–2).

[5] Average biodiesel and/or renewable diesel blend percentages based on EIA's October 2018 Short Term Energy Outlook (STEO).

[6] The statutory total renewable fuel, advanced biofuel and cellulosic biofuel requirements for 2019 are 28.0, 13.0 and 8.5 billion gallons respectively. This implies a conventional renewable fuel applicable volume (the difference between the total renewable fuel and advanced biofuel volumes, which can be satisfied by with conventional (D6) RINs) of 15.0 billion gallons, and a non-cellulosic advanced biofuel applicable volume (the difference between the advanced biofuel and cellulosic biofuel volumes, which can be satisfied with advanced (D5) RINs) of 4.5 billion gallons.

1. Approach to Setting Volume Requirements

For advanced biofuel and total renewable fuel, we are finalizing reductions based on the ''cellulosic waiver authority'' that would result in advanced biofuel and total renewable fuel volume requirements that are lower than the statutory targets by the same magnitude as the reduction in the cellulosic biofuel applicable volume. This follows the same general approach as in the 2018 final rule. The volumes for cellulosic biofuel, advanced biofuel, and total renewable fuel exceed the required volumes for these fuel types in 2018.

Section II provides a general description of our approach to setting volume requirements in today's rule, including a review of the statutory waiver authorities and our consideration of carryover Renewable Identification Numbers (RINs). Section III provides our assessment of the 2019 cellulosic biofuel volume, based on a projection of production that reflects a neutral aim at accuracy. Section IV describes our assessment of advanced biofuel and total renewable fuel. Finally, Section VI describes the 2020 BBD volume requirement, reflecting our analysis of a set of factors stipulated in CAA section 211(o)(2)(B)(ii).

2. Cellulosic Biofuel

EPA must annually determine the projected volume of cellulosic biofuel production for the following year. If the projected volume of cellulosic biofuel production is less than the applicable volume specified in section 211(o)(2)(B)(i)(III) of the statute, EPA must lower the applicable volume used to set the annual cellulosic biofuel percentage standard to the projected production volume. In this rule we are finalizing a cellulosic biofuel volume requirement of 418 million ethanol-equivalent gallons for 2019 based on our production projection. Our projection reflects consideration of the Energy Information Administration's (EIA) projection of cellulosic biofuel production in 2019; RIN generation data for past years and 2018 to date that is available to EPA through the EPA Moderated Transaction System (EMTS); the information we have received regarding individual facilities' capacities, production start dates, and biofuel production plans; a review of cellulosic biofuel production relative to EPA's projections in previous annual rules; and EPA's own engineering judgment. To project cellulosic biofuel production for 2019 we used the same basic methodology as in our proposed rule, described further in the 2018 final rule. However, we have used updated data to derive percentile values used in our production projection for liquid cellulosic biofuels and to derive the year-over-year change in the rate of production of compressed natural gas and liquified natural gas (CNG/LNG) derived from biogas that is used in the projection for CNG/LNG.

3. Advanced Biofuel

If we reduce the applicable volume of cellulosic biofuel below the volume specified in CAA section 211(o)(2)(B)(i)(III), we also have the authority to reduce the applicable volumes of advanced biofuel and total renewable fuel by the same or a lesser amount. We refer to this as the ''cellulosic waiver authority.'' The conditions that caused us to reduce the 2018 volume requirement for advanced biofuel below the statutory target remain relevant in 2019. As for 2018, we investigated the projected availability of non-cellulosic advanced biofuels in 2019. We took into account the various constraints on the ability of the market to make advanced biofuels available, the ability of the standards we set to bring about market changes in the time available, the potential impacts associated with diverting biofuels and/or biofuel feedstocks from current uses to the production of advanced biofuel used in the U.S., the fact that the biodiesel tax credit is currently not available for 2019, the tariffs on imports of biodiesel from Argentina and Indonesia, as well as the cost of advanced biofuels. Based on these considerations we are reducing the statutory volume target for advanced biofuel by the same amount as we are reducing the statutory volume target for cellulosic biofuel. This results in an advanced biofuel volume requirement for 2019 of 4.92 billion gallons, which is 630 million gallons higher than the advanced biofuel volume requirement for 2018.

4. Total Renewable Fuel

We believe that the cellulosic waiver authority is best interpreted to require equal reductions in advanced biofuel and total renewable fuel. Consistent with our proposal, we are reducing total renewable fuel by the same as the reduction in advanced biofuel, such that the resulting implied volume requirement for conventional renewable fuel will be 15 billion gallons, the same as the implied volume requirement in the statute.

5. 2020 Biomass-Based Diesel

In EISA, Congress specified increasing applicable volumes of BBD through 2012. Beyond 2012 Congress stipulated that EPA, in coordination with DOE and USDA, was to establish the BBD volume taking into consideration implementation of the program during calendar years specified in the table in CAA 211(o)(B) and various specified factors, provided that the required volume for BBD could not be less than 1.0 billion gallons. For 2013, EPA established an applicable volume of 1.28 billion gallons. For 2014 and 2015 we established the BBD volume requirement to reflect the actual volume for each of these years of 1.63 and 1.73 billion gallons.[7] For 2016 and 2017, we set the BBD volume requirements at 1.9 and 2.0 billion gallons respectively. Finally, for 2018 and 2019 the BBD volume requirement was set at 2.1 billion gallons. In this rule we are finalizing an increase to the BBD volume for 2020 to 2.43 billion gallons.

Given current and recent market conditions, the advanced biofuel volume requirement is driving the production and use of biodiesel and renewable diesel volumes over and above volumes required through the separate BBD standard, and we expect this to continue. While EPA continues to believe it is appropriate to maintain the opportunity for other advanced biofuels to compete for market share, the vast majority of the advanced biofuel obligations in recent years have been satisfied with BBD. Thus, after a review of the implementation of the program to date and considering the statutory factors, we are establishing, in coordination with USDA and DOE, an applicable volume of BBD for 2020 of 2.43 billion gallons.[8]

6. Annual Percentage Standards

The renewable fuel standards are expressed as a volume percentage and are used by each refiner and importer of fossil-based gasoline or diesel to determine their renewable fuel volume obligations.

Four separate percentage standards are required under the RFS program, corresponding to the four separate renewable fuel categories shown in Table I.A–1. The specific formulas we use in calculating the renewable fuel

[7] The 2015 BBD standard was based on actual data for the first 9 months of 2015 and on projections for the latter part of the year for which data on actual use was not available at the time.

[8] The final 330 million gallon increase for BBD would generate approximately 500 million RINs, due to the higher equivalence value of biodiesel (1.5 RINs/gallon) and renewable diesel (generally 1.7 RINs/gallon).

percentage standards are contained in the regulations at 40 CFR 80.1405. The percentage standards represent the ratio of the national applicable volume of renewable fuel volume to the national projected non-renewable gasoline and diesel volume less any gasoline and diesel attributable to small refineries granted an exemption prior to the date that the standards are set. The volume of transportation gasoline and diesel used to calculate the percentage standards was based on projections provided by EIA as required under the statute. The final applicable percentage standards for 2019 are shown in Table I.B.6–1. Detailed calculations can be found in Section VII, including the projected gasoline and diesel volumes used.

TABLE I.B.6–1—FINAL 2019 PERCENTAGE STANDARDS

	Final percentage standards
Cellulosic biofuel	0.230
Biomass-based diesel	1.73
Advanced biofuel	2.71
Renewable fuel	10.97

B. RIN Market Operations

In the rulemaking notices proposing the 2018 and 2019 RFS volume requirements, we noted that various stakeholders had raised concerns regarding lack of transparency and potential manipulation in the RIN market. We asked for comment from the public on those issues, and received multiple suggestions from stakeholders in response. Since receiving those comments, we have continued to hold meetings with stakeholders on these topics, through which we have continued to hear various perspectives on RIN market operations and potential changes.

A number of the comments received in response to the 2019 Notice of Proposed Rulemaking (NPRM) suggested increasing the amount of data related to the RIN market that EPA makes publicly available. In response to these comments, we have made additional information available through our public website.[9] The website publishes data on a number of items of interest to stakeholders, including the number of small refinery exemption petitions received, granted, and denied by year; the fuel volume exempted by year; weekly volume-weighted average RIN prices by D-code;[10] and weekly aggregated RIN transaction volumes by D-code. We intend to update these data regularly going forward. We believe this additional information will increase the transparency of the RIN market, and improve EPA's administration of the RFS program.

We also received a number of comments on the potential impacts of changing the regulations related to who may purchase RINs, the duration for which RINs could be held, and other rules related to the buying, selling, or holding of RINs. On October 9, President Trump directed EPA to undertake a CAA rulemaking that would change certain elements of the RIN compliance system under the RFS program to improve both RIN market transparency and overall functioning of the RIN market. EPA is currently considering a number of regulatory reforms that could be included in the proposal, such as: Prohibiting entities other than obligated parties from purchasing separated RINs; requiring public disclosure when RIN holdings held by an individual actor exceed specified limits; limiting the length of time a non-obligated party can hold RINs; and changing the timelines that apply to obligated parties regarding when RINs must be retired for compliance purposes. We are not currently considering changing the point of obligation in the RFS program.[11] While we have determined that RIN market issues will be addressed separately and are not being considered as part of the present rulemaking, EPA will consider comments received on this topic on the proposed 2019 annual rule as we develop this separate action.

II. Authority and Need for Waiver of Statutory Applicable Volumes

The CAA provides EPA with the authority to enact volume requirements below the applicable volume targets specified in the statute under specific circumstances. This section discusses those authorities. As described in the executive summary, we are finalizing the volume requirement for cellulosic biofuel at the level we project to be available for 2019, and an associated applicable percentage standard. For advanced biofuel and total renewable fuel, we are establishing volume requirements and associated applicable percent standards, based on use of the ''cellulosic waiver authority'' that would result in advanced biofuel and total renewable fuel volume requirements that are lower than the statutory targets by the same magnitude as the reduction in the cellulosic biofuel reduction. This would effectively maintain the implied statutory volumes for non-cellulosic advanced biofuel and conventional renewable fuel.[12]

A. Statutory Authorities for Reducing Volume Targets

In CAA section 211(o)(2), Congress specified increasing annual volume targets for total renewable fuel, advanced biofuel, and cellulosic biofuel for each year through 2022, and for BBD through 2012, and authorized EPA to set volume requirements for subsequent years in coordination with USDA and DOE, and after consideration of specified factors. However, Congress also recognized that under certain circumstances it would be appropriate for EPA to set volume requirements at a lower level than reflected in the statutory volume targets, and thus provided waiver provisions in CAA section 211(o)(7).

1. Cellulosic Waiver Authority

Section 211(o)(7)(D)(i) of the CAA provides that if EPA determines that the projected volume of cellulosic biofuel production for a given year is less than the applicable volume specified in the statute, then EPA must reduce the applicable volume of cellulosic biofuel required to the projected production volume for that calendar year. In making this projection, EPA may not ''adopt a methodology in which the risk of overestimation is set deliberately to outweigh the risk of underestimation'' but must make a projection that ''takes neutral aim at accuracy.'' *API* v. *EPA,* 706 F.3d 474, 479, 476 (D.C. Cir. 2013). Pursuant to this provision, EPA has set the cellulosic biofuel requirement lower than the statutory volume for each year since 2010. As described in Section III.D, the projected volume of cellulosic biofuel production for 2019 is less than the 8.5 billion gallon volume target in the statute. Therefore, for 2019, we are requiring a cellulosic biofuel volume lower than the statutory applicable volume, in accordance with this provision.

CAA section 211(o)(7)(D)(i) also provides EPA with the authority to reduce the applicable volume of total renewable fuel and advanced biofuel in

[9] *https://www.epa.gov/fuels-registration-reporting-and-compliance-help/public-data-renewable-fuel-standard.*

[10] Each RIN has a ''D-code'' that identifies the category of fuel (D3 for cellulosic biofuel, D7 for cellulosic diesel, D4 for biomass-based diesel, D5 for advanced biofuel, or D6 for conventional biofuel) for which the RIN was generated.

[11] EPA previously considered, and ultimately denied, petitions for reconsideration of the point of obligation in the RFS program. See ''Denial of Petitions for Rulemaking to Change the RFS Point of Obligation'' EPA–420–R–17–008, November 2017.

[12] See supra n. 6.

years when it reduces the applicable volume of cellulosic biofuel under that provision. The reduction must be less than or equal to the reduction in cellulosic biofuel. For 2019, we are reducing the applicable volumes of advanced biofuel and total renewable fuel under this authority.

EPA has used the cellulosic waiver authority to lower the cellulosic biofuel, advanced biofuel and total renewable fuel volumes every year since 2014. Further discussion of the cellulosic waiver authority, and EPA's interpretation of it, can be found in the preamble to the 2017 final rule.[13] See also *API* v. *EPA,* 706 F.3d 474 (D.C. Cir. 2013) (requiring that EPA's cellulosic biofuel projections reflect a neutral aim at accuracy); *Monroe Energy* v. *EPA,* 750 F.3d 909 (D.C. Cir. 2014) (affirming EPA's broad discretion under the cellulosic waiver authority to reduce volumes of advanced biofuel and total renewable fuel); *Americans for Clean Energy* v. *EPA* (''*ACE*''), 864 F.3d 691 (D.C. Cir. 2017) (discussed below).

In *ACE,* the court evaluated EPA's use of the cellulosic waiver authority in the 2014–2016 annual rulemaking to reduce the advanced biofuel and total renewable fuel volumes for 2014, 2015, and 2016. There, EPA used the cellulosic waiver authority to reduce the advanced biofuel volume to a level that was reasonably attainable, and then provided a comparable reduction under this authority for total renewable fuel.[14] The Court of Appeals for the District of Columbia, relying on the analysis in *Monroe Energy,* reaffirmed that EPA enjoys ''broad discretion'' under the cellulosic waiver authority ''to consider a variety of factors—including demand-side constraints in the advanced biofuels market.'' [15] The Court noted that the only textual limitation on the use of the cellulosic waiver authority is that it cannot exceed the amount of the reduction in cellulosic biofuel.[16] The Court contrasted the general waiver authority under CAA section 211(o)(7)(A) and the biomass based diesel waiver authority under CAA section 211(o)(7)(E), which ''detail the considerations and procedural steps that EPA must take before waiving fuel requirements,'' with the cellulosic waiver authority, which identifies no factors regarding reductions in advanced and total renewable fuel other than the limitation that any such reductions may not exceed the reduction in cellulosic biofuel volumes.[17] The Court also concluded that the scope of EPA's discretionary authority to reduce advanced and total volumes is the same under the cellulosic waiver provision whether EPA is declining to exercise its authority to waive volumes, or choosing to do so.[18]

In this action we are using the cellulosic waiver authority to reduce the statutory volume targets for advanced biofuels and total renewable fuel by equal amounts, consistent with our long-held interpretation of this provision and our approach in setting the 2014–2018 standards. This approach considers the Congressional objectives reflected in the volume tables in the statute, and the environmental objectives that generally favor the use of advanced biofuels over non-advanced biofuels. See 81 FR 89752–89753 (December 12, 2016). See also 78 FR 49809–49810 (August 15, 2013); 80 FR 77434 (December 14, 2015). We are concluding, as described in Section IV, that it is appropriate for EPA to reduce the advanced biofuel volume under the cellulosic waiver authority by the same quantity as the reduction in cellulosic biofuel, and to provide an equal reduction under the cellulosic waiver authority in the applicable volume of total renewable fuel. We are taking this action both because we do not believe that the statutory volumes can be achieved, and because we do not believe that backfilling of the shortfall in cellulosic with advanced biofuel would be appropriate due to high costs, as well as other factors such as feedstock switching and/or diversion of foreign advanced biofuels. The volumes of advanced and total renewable fuel resulting from this exercise of the cellulosic waiver authority provide for an implied volume allowance for conventional renewable fuel of 15 billion gallons, and an implied volume allowance for non-cellulosic advanced biofuel of 4.5 billion gallons, equal to the implied statutory volumes for 2019. We also believe that the volume of renewable fuel made available after reductions using the cellulosic waiver authority is attainable, as discussed in Section IV.

2. General Waiver Authority

Section 211(o)(7)(A) of the CAA provides that EPA, in consultation with the Secretary of Agriculture and the Secretary of Energy, may waive the applicable volumes specified in the Act in whole or in part based on a petition by one or more States, by any person subject to the requirements of the Act, or by the EPA Administrator on his own motion. Such a waiver must be based on a determination by the Administrator, after public notice and opportunity for comment that: (1) Implementation of the requirement would severely harm the economy or the environment of a State, a region, or the United States; or (2) there is an inadequate domestic supply.

EPA received comments suggesting that EPA should use the general waiver to further reduce volumes under findings of inadequate domestic supply, and/or severe harm to the economy or environment. Based on our review of the comments and updated data, and consistent with EPA's rationale and decisions in setting the 2018 standards, we decline to exercise our discretion to reduce volumes under the general waiver authority. Further discussion of these issues is found in the RTC document and a memorandum to the docket.[19]

B. Treatment of Carryover RINs

Consistent with our approach in the final rules establishing the RFS standards for 2013 through 2018, we have also considered the availability and role of carryover RINs in evaluating whether we should exercise our discretion to use our waiver authorities in setting the volume requirements for 2019. Neither the statute nor EPA regulations specify how or whether EPA should consider the availability of carryover RINs in exercising the cellulosic waiver authority.[20] As noted in the context of the rules establishing the RFS standards for 2014 through 2018, we believe that a bank of carryover RINs is extremely important

[13] See 81 FR 89752–89753 (December 12, 2016).

[14] See 80 FR 77433–34 (December 14, 2015).

[15] *ACE,* 864 F.3d at 730.

[16] *Id.* at 733.

[17] *Id.*

[18] *Id.* at 734.

[19] See ''Endangered Species Act No Effect Finding and Determination of Severe Environmental Harm under the General Waiver Authority for the 2019 Final Rule'' Memorandum from EPA Staff to EPA Docket EPA–HQ–OAR–2018–0167.

[20] CAA section 211(o)(5) requires that EPA establish a credit program as part of its RFS regulations, and that the credits be valid to show compliance for 12 months as of the date of generation. EPA implemented this requirement though the use of RINs, which can be used to demonstrate compliance for the year in which they are generated or the subsequent compliance year. Obligated parties can obtain more RINs than they need in a given compliance year, allowing them to ''carry over'' these excess RINs for use in the subsequent compliance year, although use of these carryover RINs is limited to 20 percent of the obligated party's renewable volume obligation (RVO). For the bank of carryover RINs to be preserved from one year to the next, individual carryover RINs are used for compliance before they expire and are essentially replaced with newer vintage RINs that are then held for use in the next year. For example, if the volume of the collective carryover RIN bank is to remain unchanged from 2017 to 2018, then all of the vintage 2017 carryover RINs must be used for compliance in 2018, or they will expire. However, the same volume of 2018 RINs can then be ''banked'' for use in 2019.

in providing obligated parties compliance flexibility in the face of substantial uncertainties in the transportation fuel marketplace, and in providing a liquid and well-functioning RIN market upon which success of the entire program depends.[21] Carryover RINs provide flexibility in the face of a variety of circumstances that could limit the availability of RINs, including weather-related damage to renewable fuel feedstocks and other circumstances potentially affecting the production and distribution of renewable fuel.[22] On the other hand, carryover RINs can be used for compliance purposes, and in the context of the 2013 RFS rulemaking we noted that an abundance of carryover RINs available in that year (2.666 billion RINs or approximately 16 percent of the total renewable fuel volume requirement for 2013), together with possible increases in renewable fuel production and import, justified maintaining the advanced and total renewable fuel volume requirements for that year at the levels specified in the statute.[23] EPA's approach to the consideration of carryover RINs in exercising our cellulosic waiver authority was affirmed in *Monroe Energy* and *ACE.*[24]

An adequate RIN bank serves to make the RIN market liquid. Just as the economy as a whole functions best when individuals and businesses prudently plan for unforeseen events by maintaining inventories and reserve money accounts, we believe that the RFS program functions best when sufficient carryover RINs are held in reserve for potential use by the RIN holders themselves, or for possible sale to others that may not have established their own carryover RIN reserves. Were there to be no RINs in reserve, then even minor disruptions or other shortfalls in renewable fuel production or distribution relative to petroleum fuel supply, or higher than expected transportation fuel demand (requiring greater volumes of renewable fuel to comply with the percentage standards that apply to all volumes of transportation fuel, including the unexpected volumes) could lead to the need for a new waiver of the standards, undermining the market certainty so critical to the RFS program. Moreover, a significant drawdown of the carryover RIN bank leading to a scarcity of RINs may stop the market from functioning in an efficient manner (*i.e.,* one in which there are a sufficient number of reasonably available RINs for obligated parties seeking to purchase them), even where the market overall could satisfy the standards. For all of these reasons, the collective carryover RIN bank provides a needed programmatic buffer that both facilitates individual compliance and provides for smooth overall functioning of the program.[25]

1. Carryover RIN Bank Size

At the time of the 2019 NPRM, we estimated that there were approximately 3.06 billion total carryover RINs available and proposed that carryover RINs should not be counted on to avoid or minimize the need to reduce the 2019 statutory volume targets. We also proposed that the 2019 volume should not be set at levels that would intentionally lead to a drawdown in the bank of carryover RINs (*e.g.,* volumes that were significantly beyond the market's ability to supply renewable fuels).[26]

Since that time, obligated parties have performed their attest engagements and submitted revised compliance reports for the 2017 compliance year and we now estimate that there are currently approximately 2.59 billion total carryover RINs available,[27] a decrease of 470 million RINs from the 3.06 billion total carryover RINs that were estimated to be available in the 2019 NPRM.[28] This decrease in the total carryover RIN bank compared to that projected in the 2019 NPRM results from various factors, including market factors, regulatory and enforcement actions, and judicial proceedings. This estimate also includes the millions of RINs that were not required to be retired by small refineries that were granted hardship exemptions in recent years,[29] along with the RINs that Philadelphia Energy Solutions Refining and Marketing, LLC (''PESRM'') was not required to retire as part of its bankruptcy settlement agreement.[30] This total volume of carryover RINs is approximately 13 percent of the total renewable fuel volume requirement that EPA is finalizing for 2019, which is less than the 20 percent maximum limit permitted by the regulations to be carried over for use in complying with the 2019 standards.[31]

The above discussion applies to total carryover RINs; we have also considered the available volume of advanced biofuel carryover RINs. At the time of the 2019 NPRM, we estimated that there were approximately 700 million advanced carryover RINs available. Since that time, obligated parties have performed their attest engagements and submitted revised compliance reports for the 2017 compliance year and we now estimate that there are currently approximately 600 million advanced carryover RINs available,[32] a decrease of 100 million RINs from the 700 million total carryover RINs that were estimated to be available in the 2019 NPRM.[33] This volume of advanced carryover RINs is approximately 12 percent of the advanced renewable fuel volume requirement that EPA is finalizing for 2019, which is less than the 20 percent maximum limit permitted by the regulations to be carried over for use in complying with the 2019 standards.[34]

However, there remains considerable uncertainty surrounding the number of carryover RINs that will be available for use in 2019 for a number of reasons, including the potential impact of any future action to address the remand in *ACE,* the possibility of additional small

[21] See 80 FR 77482–87 (December 14, 2015), 81 FR 89754–55 (December 12, 2016), and 82 FR 58493–95 (December 12, 2017).

[22] See 72 FR 23900 (May 1, 2007), 80 FR 77482–87 (December 14, 2015), 81 FR 89754–55 (December 12, 2016), and 82 FR 58493–95 (December 12, 2017).

[23] See 78 FR 49794–95 (August 15, 2013).

[24] *Monroe Energy* v. *EPA,* 750 F.3d 909 (D.C. Cir. 2014), *ACE,* 864 F.3d at 713.

[25] Here we use the term ''buffer'' as shorthand reference to all of the benefits that are provided by a sufficient bank of carryover RINs.

[26] See 83 FR 32024 (July 10, 2018).

[27] The calculations performed to estimate the number of carryover RINs currently available can be found in the memorandum, ''Carryover RIN Bank Calculations for 2019 Final Rule,'' available in the docket.

[28] See ''Carryover RIN Bank Calculations for 2019 NPRM,'' Docket Item No. EPA–HQ–OAR–2018–0167–0043.

[29] Information about the number of small refinery exemptions granted and the volume of RINs not required to be retired as a result of those exemptions can be found at *https://www.epa.gov/fuels-registration-reporting-and-compliance-help/rfs-small-refinery-exemptions.*

[30] Per PESRM's bankruptcy filings, PESRM had an RVO of 467 million RINs for 2017 (including its deficit carryforward from 2016). Pursuant to the settlement agreement, which was based on the unique facts and circumstances present in this case, including the insolvency and risk of liquidation, PESRM agreed to retire 138 million RINs to meet its 2017 RVO and the portion of its 2018 RVO during the bankruptcy proceedings (approximately 97 million RINs). See docket for PES Holdings, LLC, 1:18bk10122, ECF Document Nos. 244 (proposed settlement agreement), 347 (United States' motion to approve proposed settlement agreement), 376 (order approving proposed settlement agreement), and 510 (Stipulation between the Debtors and the United States on behalf of the Environmental Protection Agency relating to Renewable Identification Number Retirement Deadlines under Consent Decree and Environmental Settlement Agreement) (Bankr. D. Del.). PESRM has emerged from bankruptcy and EPA does not anticipate further relief being granted under the RFS program.

[31] See 40 CFR 80.1427(a)(5).

[32] The calculations performed to estimate the number of carryover RINs currently available can be found in the memorandum, ''Carryover RIN Bank Calculations for 2019 Final Rule,'' available in the docket.

[33] See ''Carryover RIN Bank Calculations for 2019 NPRM,'' Docket Item No. EPA–HQ–OAR–2018–0167–0043.

[34] See 40 CFR 80.1427(a)(5).

refinery exemptions, and the impact of 2018 RFS compliance on the bank of carryover RINs. In addition, we note that there have been enforcement actions in past years that have resulted in the retirement of carryover RINs to make up for the generation and use of invalid RINs and/or the failure to retire RINs for exported renewable fuel. Future enforcement actions could have similar results, and require that obligated parties and/or renewable fuel exporters settle past enforcement-related obligations in addition to the annual standards, thereby potentially creating demand for RINs greater than can be accommodated through actual renewable fuel blending in 2019. In light of these uncertainties, the net result could be a bank of total carryover RINs larger or smaller than 13 percent of the 2019 total renewable fuel volume requirement, and a bank of advanced carryover RINs larger or smaller than 12 percent of the 2019 advanced biofuel volume requirement.

2. EPA's Decision Regarding the Treatment of Carryover RINs

We have evaluated the volume of carryover RINs currently available and considered whether they would justify a reduced use of our cellulosic waiver authority in setting the 2019 volume requirements in order to intentionally draw down the carryover RIN bank. We also carefully considered the comments received, including comments on the role of carryover RINs under our waiver authorities and the policy implications of our decision.[35] For the reasons described throughout Section II.B, we do not believe we should intentionally draw down the bank of carryover RINs and limit the exercise of our cellulosic waiver authority. The current bank of carryover RINs provides an important and necessary programmatic buffer that will both facilitate individual compliance and provide for smooth overall functioning of the program. We believe that a balanced consideration of the possible role of carryover RINs in achieving the statutory volume objectives for advanced and total renewable fuels, versus maintaining an adequate bank of carryover RINs for important programmatic functions, is appropriate when EPA exercises its discretion under the cellulosic waiver authority, and that the statute does not specify the extent to which EPA should require a drawdown in the bank of carryover RINs when it exercises this authority. Therefore, for the reasons noted above and consistent with the approach we took in the final rules establishing the RFS standards for 2014 through 2018, we have decided to maintain our proposed approach and are making a determination to not set the 2019 volume requirements at levels that would envision an intentional drawdown in the bank of carryover RINs. We note that we may or may not take a similar approach in future years; we will assess the situation on a case-by-case basis going forward and take into account the size of the carryover RIN bank in the future and any lessons learned from implementing past rules.

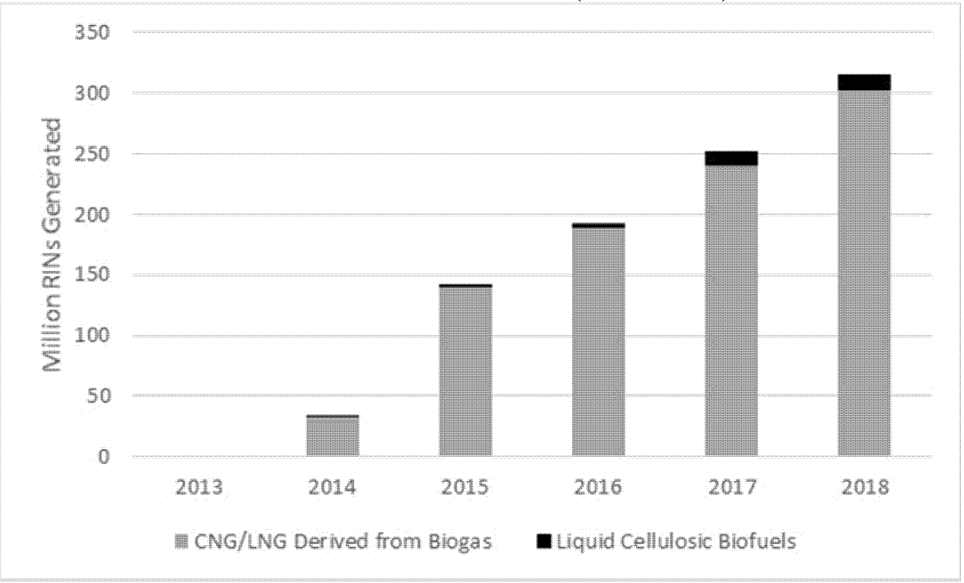
[35] In their comments on the 2019 NPRM, parties generally expressed two opposing points of view. Commenters representing obligated parties supported EPA's proposed decision to not assume a drawdown in the bank of carryover RINs in determining the appropriate volume requirements, reiterating the importance of maintaining the carryover RIN bank in order to provide obligated parties with necessary compliance flexibilities, better market trading liquidity, and a cushion against future program uncertainty. Commenters representing renewable fuel producers, however, stated that not accounting for carryover RINs goes against Congressional intent of the RFS program and deters investment in cellulosic and advanced biofuels. A full description of comments received, and our detailed responses to them, is available in the RTC document in the docket.

III. Cellulosic Biofuel Volume for 2019

In the past several years, production of cellulosic biofuel has continued to increase. Cellulosic biofuel production reached record levels in 2017, driven largely by CNG and LNG derived from biogas. Production volumes through September 2018 suggest production in 2018 will exceed production volumes in 2017.[36] Production of liquid cellulosic biofuel has also increased in recent years, even as the total production of liquid cellulosic biofuels remains much smaller than the production volumes of CNG and LNG derived from biogas. This section describes our assessment of the volume of cellulosic biofuel that we project will be produced or imported into the U.S. in 2019, and some of the uncertainties associated with those volumes.

[36] The majority of the cellulosic RINs generated for CNG/LNG are sourced from biogas from landfills; however, the biogas may come from a variety of sources including municipal wastewater treatment facility digesters, agricultural digesters, separated municipal solid waste (MSW) digesters, and the cellulosic components of biomass processed in other waste digesters.

Figure III-1
Cellulosic RINs Generated (2013-2018)[a]



[a]Cellulosic RIN generation data from EMTS; 2018 volumes are projected based on data through September 2018

In order to project the volume of cellulosic biofuel production in 2019, we considered EIA's projection of cellulosic biofuel production in 2019, the accuracy of the methodologies used to project cellulosic biofuel production in previous years, data reported to EPA through EMTS, and information we collected through meetings with representatives of facilities that have produced or have the potential to produce qualifying volumes of cellulosic biofuel in 2019 for consumption as transportation fuel, heating oil, or jet fuel in the U.S.

There are two main elements to the cellulosic biofuel production projection: Liquid cellulosic biofuel and CNG/LNG derived from biogas. To project the range of potential production volumes of liquid cellulosic biofuel we used the same general methodology as the methodology used in the proposed rule, as well as the 2018 final rule. However, we have adjusted the percentile values used to select a point estimate within a projected production range for each group of companies based on updated information (through the end of September 2018) with the objective of improving the accuracy of the projections. To project the production of cellulosic biofuel RINs for CNG/LNG derived from biogas, we used the same general year-over-year growth rate methodology as in the 2019 proposed rule and 2018 final rule, with updated RIN generation data through September 2018. This methodology reflects the mature status of this industry, the large number of facilities registered to generate cellulosic biofuel RINs from these fuels, and EPA's continued attempts to refine its methodology to yield estimates that are as accurate as possible. This methodology is an improvement on the methodology that EPA used to project cellulosic biofuel production for CNG/LNG derived from biogas in the 2017 and previous years (see Section III.B below for a further discussion of the accuracy of EPA's methodology in previous years). The methodologies used to project the production of liquid cellulosic biofuels and cellulosic CNG/LNG derived from biogas are described in more detail in Sections III.D–1 and III.D–2 below.

The balance of this section is organized as follows. Section III.A provides a brief description of the statutory requirements. Section III.B reviews the accuracy of EPA's projections in prior years, and also discusses the companies the EPA assessed in the process of projecting qualifying cellulosic biofuel production in the U.S. in 2018 in Section III.B. Section III.C discusses EIA's projection of cellulosic biofuel production for 2019 and how this projection compares to EPA's projection. Section III.D discusses the methodologies used by EPA to project cellulosic biofuel production in 2019 and the resulting projection of 381 million ethanol-equivalent gallons.

A. Statutory Requirements

CAA section 211(o)(2)(B)(i)(III) states the statutory volume targets for cellulosic biofuel. The volume of cellulosic biofuel specified in the statute for 2019 is 8.5 billion gallons. The statute provides that if EPA determines, based on a letter provided to the EPA by EIA, that the projected volume of cellulosic biofuel production in a given year is less than the statutory volume, then EPA shall reduce the applicable volume of cellulosic biofuel to the projected volume available during that calendar year.[37]

In addition, if EPA reduces the required volume of cellulosic biofuel below the level specified in the statute, we may reduce the applicable volumes of advanced biofuels and total renewable fuel by the same or a lesser volume,[38] and we are also required to make cellulosic waiver credits

[37] CAA section 211(o)(7)(D)(i). The U.S. Court of Appeals for the District of Columbia Circuit evaluated this requirement in *API* v. *EPA,* 706 F.3d 474, 479–480 (D.C. Cir. 2013), in the context of a challenge to the 2012 cellulosic biofuel standard. The Court stated that in projecting potentially available volumes of cellulosic biofuel EPA must apply an ''outcome-neutral methodology'' aimed at providing a prediction of ''what will *actually* happen.'' *Id.* at 480, 479. EPA has consistently interpreted the term ''projected volume of cellulosic biofuel production'' in CAA section 211(o)(7)(D)(i) to include volumes of cellulosic biofuel likely to be made available in the U.S., including from both domestic production and imports (see 80 FR 77420 (December 14, 2015) and 81 FR 89746 (December 12, 2016)). We do not believe it would be reasonable to include in the projection all cellulosic biofuel produced throughout the world, regardless of likelihood of import to the U.S., since volumes that are not imported would not be available to obligated parties for compliance and including them in the projection would render the resulting volume requirement and percentage standards unachievable.

[38] CAA section 211(o)(7)(D)(i).

available.[39] Our consideration of the 2019 volume requirements for advanced biofuel and total renewable fuel is presented in Section IV.

B. Cellulosic Biofuel Industry Assessment

In this section, we first explain our general approach to assessing facilities or groups of facilities (which we collectively refer to as ''facilities'') that have the potential to produce cellulosic biofuel in 2019. We then review the accuracy of EPA's projections in prior years. Next, we discuss the criteria used to determine whether to include potential domestic and foreign sources of cellulosic biofuel in our projection for 2019. Finally, we provide a summary table of all facilities that we expect to produce cellulosic biofuel in 2019.

In order to project cellulosic biofuel production for 2019 we have tracked the progress of a number of potential cellulosic biofuel production facilities, located both in the U.S. and in foreign countries. As we have done in previous years, we have focused on facilities with the potential to produce commercial-scale volumes of cellulosic biofuel rather than small research and development (R&D) or pilot-scale facilities.[40] We considered a number of factors, including EIA's projection of cellulosic biofuel production in 2019, information from EMTS, the registration status of potential biofuel production facilities as cellulosic biofuel producers in the RFS program, publicly available information (including press releases and news reports), and information provided by representatives of potential cellulosic biofuel producers, in making our projection of cellulosic biofuel production for 2019. As discussed in greater detail below, our projection of liquid cellulosic biofuel is based on a facility-by-facility assessment of each of the likely sources of cellulosic biofuel in 2019, while our projection of CNG/LNG derived from biogas is based on an industry wide assessment. To make a determination of which facilities are most likely to produce liquid cellulosic biofuel and generate cellulosic biofuel RINs in 2019, each potential producer of liquid cellulosic biofuel was investigated further to determine the current status of its facilities and its likely cellulosic biofuel production and RIN generation volumes for 2019. Both in our discussions with representatives of individual companies and as part of our internal evaluation process we gathered and analyzed information including, but not limited to, the funding status of these facilities, current status of the production technologies, anticipated construction and production ramp-up periods, facility registration status, and annual fuel production and RIN generation targets.

1. Review of EPA's Projection of Cellulosic Biofuel in Previous Years

As an initial matter, it is useful to review the accuracy of EPA's past cellulosic biofuel projections. The record of actual cellulosic biofuel production and EPA's projected production volumes from 2015–2018 are shown in Table III.B–1 below. These data indicate that EPA's projection was lower than the actual number of cellulosic RINs made available in 2015,[41] higher than the actual number of RINs made available in 2016 and 2017, and lower than the actual number of RINs projected to be made available in 2018. The fact that the projections made using this methodology have been somewhat inaccurate, under-estimating the actual number of RINs made available in 2015 and 2018, and over-estimating in 2016 and 2017, reflects the inherent difficulty with projecting cellulosic biofuel production. It also emphasizes the importance of continuing to make refinements to our projection methodology in order to make our projections more accurate.

TABLE III.B.1–1—PROJECTED AND ACTUAL CELLULOSIC BIOFUEL PRODUCTION (2015–2018); MILLION GALLONS [a]

	Projected volume [b]			Actual production volume [c]		
	Liquid cellulosic biofuel	CNG/LNG derived from biogas	Total cellulosic biofuel [d]	Liquid cellulosic biofuel	CNG/LNG derived from biogas	Total cellulosic biofuel [d]
2015 [e]	2	33	35	0.5	52.8	53.3
2016	23	207	230	4.1	186.2	190.3
2017	13	298	311	11.8	239.5	251.3
2018 [f]	14	274	288	14.0	309.0	323.0

[a] As noted in Section III.A. above, EPA has consistently interpreted the term ''projected volume of cellulosic biofuel production'' to include volumes of cellulosic biofuel likely to be made available in the U.S., including from both domestic production and imports. The volumes in this table therefore include both domestic production of cellulosic biofuel and imported cellulosic biofuel.

[b] Projected volumes for 2015 and 2016 can be found in the 2014–2016 Final Rule (80 FR 77506, 77508, December 14, 2015); projected volumes for 2017 can be found in the 2017 Final Rule (81 FR 89760, December 12, 2016); projected volumes for 2018 can be found in the 2018 Final Rule (82 FR 58503, December 12, 2017).

[c] Actual production volumes are the total number of RINs generated minus the number of RINs retired for reasons other than compliance with the annual standards, based on EMTS data.

[d] Total cellulosic biofuel may not be precisely equal to the sum of liquid cellulosic biofuel and CNG/LNG derived from biogas due to rounding.

[e] Projected and actual volumes for 2015 represent only the final 3 months of 2015 (October–December) as EPA used actual RIN generation data for the first 9 months of the year.

[f] Actual production in 2018 is projected based on actual data from January–September 2018 and a projection of likely production for October–December 2018.

EPA's projections of liquid cellulosic biofuel were higher than the actual volume of liquid cellulosic biofuel produced each year from 2015 to 2017.[42] As a result of these over-projections, and in an effort to take into account the most recent data available and make the liquid cellulosic biofuel projections more accurate, EPA adjusted our methodology in the 2018 final

[39] See CAA section 211(o)(7)(D)(ii); 40 CFR 80.1456.

[40] For a further discussion of EPA's decision to focus on commercial scale facilities, rather than R&D and pilot scale facilities, see the 2019 proposed rule (83 FR 32031, July 10, 2018).

[41] EPA only projected cellulosic biofuel production for the final three months of 2015, since data on the availability of cellulosic biofuel RINs (D3+D7) for the first nine months of the year were available at the time the analyses were completed for the final rule.

[42] We note, however, that because the projected volume of liquid cellulosic biofuel in each year was very small relative to the total volume of cellulosic biofuel, these over-projections had a minimal impact on the accuracy of our projections of cellulosic biofuel for each of these years.

rule.[43] The adjustments to our methodology adopted in the 2018 final rule appear to have resulted in a projection that is very close to the volume of liquid cellulosic biofuel expected to be produced in 2018 based on data through September 2018. In this 2019 final rule we are again using percentile values based on actual production in previous years, relative to the projected volume of liquid cellulosic biofuel in these years (the approach first used in 2018). We have adjusted the percentile values to project liquid cellulosic biofuel production based on actual liquid cellulosic biofuel production in 2016 to 2018. Use of this updated data results in slightly different percentile values than we used to project production of liquid cellulosic biofuel in the 2019 proposed rule and the 2018 final rule. We believe that the use of the methodology (described in more detail in Section III.D.1 below), with the adjusted percentile values, results in a projection that reflects a neutral aim at accuracy since it accounts for expected growth in the near future by using historical data that is free of any subjective bias.

We next turn to the projection of CNG/LNG derived from biogas. For 2018, EPA for the first time used an industry-wide approach, rather than an approach that projects volumes for individual companies or facilities, to project the production of CNG/LNG derived from biogas. EPA used a facility-by-facility approach to project the production of CNG/LNG derived from biogas from 2015–2017. Notably this methodology resulted in significant over-estimates of CNG/LNG production in 2016 and 2017, leading EPA to develop the alternative industry wide projection methodology first used in 2018. This updated approach reflects the fact that this industry is far more mature than the liquid cellulosic biofuel industry, with a far greater number of potential producers of CNG/LNG derived from biogas. In such cases, industry-wide projection methods can be more accurate than a facility-by-facility approach, especially as macro market and economic factors become more influential on total production than the success or challenges at any single facility. The industry wide projection methodology slightly under-projected the production of CNG/LNG derived from biogas in 2018. However, the difference between the projected and actual production volume of these fuels was smaller than in 2017.

As described in Section III.D.2 below, EPA is again projecting production of CNG/LNG derived from biogas using the industry wide approach. We calculate a year-over-year rate of growth in the renewable CNG/LNG industry by comparing RIN generation for CNG/LNG derived from biogas from October 2016–September 2017 to the RIN generation for these same fuels from October 2017–September 2018 (the most recent month for which data are available). We then apply this year-over-year growth rate to the total number of cellulosic RINs generated and available to be used for compliance with the annual standards in 2017 to estimate the production of CNG/LNG derived from biogas in 2019.[44] We have applied the growth rate to the number of available 2017 RINs generated for CNG/LNG derived from biogas as data from this year allows us to adequately account for not only RIN generation, but also for RINs retired for reasons other than compliance with the annual standards. While more recent RIN generation data is available, the retirement of RINs for reasons other than compliance with the annual standards generally lags RIN generation, sometimes by up to a year or more.[45] Should this methodology continue to under predict in the future as it did in 2018, then we may need to revisit the methodology, but with only 2018 to compare to it is premature to make any adjustments.

2. Potential Domestic Producers

There are several companies and facilities[46] located in the U.S. that have either already begun producing cellulosic biofuel for use as transportation fuel, heating oil, or jet fuel at a commercial scale, or are anticipated to be in a position to do so at some time during 2019. The financial incentive provided by cellulosic biofuel RINs,[47] combined with the fact that to date nearly all cellulosic biofuel produced in the U.S. has been used domestically[48] and all the domestic facilities we have contacted in deriving our projections intend to produce fuel on a commercial scale for domestic consumption and plan to use approved pathways, gives us a high degree of confidence that cellulosic biofuel RINs will be generated for any fuel produced by domestic commercial scale facilities. To generate RINs, each of these facilities must be registered with EPA under the RFS program and comply with all the regulatory requirements. This includes using an approved RIN-generating pathway and verifying that their feedstocks meet the definition of renewable biomass. Most of the domestic companies and facilities considered in our assessment of potential cellulosic biofuel producers in 2019 have already successfully completed facility registration, and have successfully generated RINs.[49] A brief description of each of the domestic companies (or group of companies for cellulosic CNG/LNG producers and the facilities using Edeniq's technology) that EPA believes may produce commercial-scale volumes of RIN generating cellulosic biofuel by the end of 2019 can be found in a memorandum to the docket for this final rule.[50] General information on each of these companies or group of companies considered in our projection of the potentially available volume of cellulosic biofuel in 2019 is summarized in Table III.B.3–1 below.

3. Potential Foreign Sources of Cellulosic Biofuel

In addition to the potential sources of cellulosic biofuel located in the U.S., there are several foreign cellulosic biofuel companies that may produce cellulosic biofuel in 2019. These include facilities owned and operated by Beta Renewables, Enerkem, Ensyn, GranBio, and Raizen. All of these facilities use fuel production pathways that have been approved by EPA for cellulosic RIN generation provided eligible sources of renewable feedstock are used and other regulatory requirements are satisfied. These

[43] 82 FR 58486 (December 12, 2017).

[44] To project the volume of CNG/LNG derived from biogas in 2019 we multiply the number of 2017 RINs generated for these fuels and available to be used for compliance with the annual standards by the calculated growth rate to project production of these fuels in 2018, and then multiply the resulting number by the growth rate again to project the production of these fuels in 2019.

[45] We note that we do not ignore this more recent data, but rather use it to calculate the year-over-year growth rate used to project the production of CNG/LNG derived from biogas in 2019.

[46] The volume projection from CNG/LNG producers and facilities using Edeniq's production technology do not represent production from a single company or facility, but rather a group of facilities utilizing the same production technology.

[47] According to data from Argus Media, the price for 2018 cellulosic biofuel RINs averaged $2.40 in 2018 (through September 2018). Alternatively, obligated parties can satisfy their cellulosic biofuel obligations by purchasing an advanced (or biomass-based diesel) RIN and a cellulosic waiver credit. The price for 2017 advanced biofuel RINs averaged $0.55 in through September 2018 while the price for a 2018 cellulosic waiver credit is $1.96 (EPA–420–B–17–036).

[48] The only known exception was a small volume of fuel produced at a demonstration scale facility exported to be used for promotional purposes.

[49] Most of the facilities listed in Table III.B.3–1 are registered to produce cellulosic (D3 or D7) RINs with the exception of several of the producers of CNG/LNG derived from biogas and Ensyn's Port-Cartier, Quebec facility.

[50] ''Cellulosic Biofuel Producer Company Descriptions (November 2018),'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

companies would therefore be eligible to register their facilities under the RFS program and generate RINs for any qualifying fuel imported into the U.S. While these facilities may be able to generate RINs for any volumes of cellulosic biofuel they import into the U.S., demand for the cellulosic biofuels they produce is expected to be high in their own local markets.

EPA's projection of cellulosic biofuel production in 2019 includes cellulosic biofuel that is projected to be imported into the U.S. in 2019. For the purposes of this final rule we have considered all the registered foreign facilities under the RFS program to be potential sources of cellulosic biofuel in 2019. We believe that due to the strong demand for cellulosic biofuel in local markets, the significant technical challenges associated with the operation of cellulosic biofuel facilities, and the time necessary for potential foreign cellulosic biofuel producers to register under the RFS program and arrange for the importation of cellulosic biofuel to the U.S., cellulosic biofuel imports from foreign facilities not currently registered to generate cellulosic biofuel RINs are generally highly unlikely in 2019. For purposes of our 2019 cellulosic biofuel projection we have, with one exception (described below), excluded potential volumes from foreign cellulosic biofuel production facilities that are not currently registered under the RFS program.

Cellulosic biofuel produced at three foreign facilities (Ensyn's Renfrew facility, GranBio's Brazilian facility, and Raizen's Brazilian facility) generated cellulosic biofuel RINs for fuel exported to the U.S. in 2017 and/or 2018; projected volumes from each of these facilities are included in our projection of available volumes for 2019. EPA has also included projected volume from two additional foreign facilities. One of these facilities has completed the registration process as a cellulosic biofuel producer (Enerkem's Canadian facility). The other facility (Ensyn's Port-Cartier, Quebec facility), while not yet registered as a cellulosic biofuel producer, is owned by a Ensyn, a company that has previously generated cellulosic biofuel RINs using the same technology at a different facility. We believe that it is appropriate to include volume from these facilities in light of their proximity to the U.S., the proven technology used by these facilities, the volumes of cellulosic biofuel exported to the U.S. by the company in previous years (in the case of Ensyn), and the company's stated intentions to market fuel produced at these facilities to qualifying markets in the U.S. All of the facilities included in EPA's cellulosic biofuel projection for 2019 are listed in Table III.B.3–1 below.

4. Summary of Volume Projections for Individual Companies

General information on each of the cellulosic biofuel producers (or group of producers, for producers of CNG/LNG derived from biogas and producers of liquid cellulosic biofuel using Edeniq's technology) that factored into our projection of cellulosic biofuel production for 2019 is shown in Table III.B.3–1. This table includes both facilities that have already generated cellulosic RINs, as well as those that have not yet generated cellulosic RINs, but are projected to do so by the end of 2019. As discussed above, we have focused on commercial-scale cellulosic biofuel production facilities. Each of these facilities (or group of facilities) is discussed further in a memorandum to the docket.[51]

TABLE III.B.4–1—PROJECTED PRODUCERS OF CELLULOSIC BIOFUEL IN 2019

Company name	Location	Feedstock	Fuel	Facility capacity (million gallons per year)[52]	Construction start date	First production[53]
CNG/LNG Producers[54]	Various	Biogas	CNG/LNG	Various	Various	August 2014.
Edeniq	Various	Corn Kernel Fiber	Ethanol	Various	Various	October 2016.
Enerkem	Edmonton, AL, Canada	Separated MSW	Ethanol	10[55]	2012	September 2017.[56]
Ensyn	Renfrew, ON, Canada	Wood Waste	Heating Oil	3	2005	2014.
Ensyn	Port-Cartier, QC, Canada	Wood Waste	Heating Oil	10.5	June 2016	January 2018.
GranBio	São Miguel dos Campos, Brazil.	Sugarcane bagasse	Ethanol	21	Mid 2012	September 2014.
Poet-DSM	Emmetsburg, IA	Corn Stover	Ethanol	20	March 2012	4Q 2015.
QCCP/Syngenta	Galva, IA	Corn Kernel Fiber	Ethanol	4	Late 2013	October 2014.
Raizen	Piracicaba City, Brazil	Sugarcane bagasse	Ethanol	11	January 2014	July 2015.

[51] ''Cellulosic Biofuel Producer Company Descriptions (November 2018),'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[52] The Facility Capacity is generally equal to the nameplate capacity provided to EPA by company representatives or found in publicly available information. Capacities are listed in physical gallons (rather than ethanol-equivalent gallons). If the facility has completed registration and the total permitted capacity is lower than the nameplate capacity then this lower volume is used as the facility capacity. For companies generating RINs for CNG/LNG derived from biogas the Facility Capacity is equal to the lower of the annualized rate of production of CNG/LNG from the facility at the time of facility registration or the sum of the volume of contracts in place for the sale of CNG/LNG for use as transportation fuel (reported as the actual peak capacity for these producers).

[53] Where a quarter is listed for the first production date EPA has assumed production begins in the middle month of the quarter (*i.e.,* August for the 3rd quarter) for the purposes of projecting volumes.

[54] For more information on these facilities see ''November 2018 Assessment of Cellulosic Biofuel Production from Biogas (2019),'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[55] The nameplate capacity of Enerkem's facility is 10 million gallons per year. However, we anticipate that a portion of their feedstock will be non-biogenic MSW. RINs cannot be generated for the portion of the fuel produced from non-biogenic feedstocks. We have taken this into account in our production projection for this facility (See ''November 2018 Liquid Cellulosic Biofuel Projections for 2018 CBI'').

[56] This date reflects the first production of ethanol from this facility. The facility began production of methanol in 2015.

C. Projection From the Energy Information Administration

Section 211(o)(3)(A) of the CAA requires EIA to ''provide to the Administrator of the Environmental Protection Agency an estimate, with respect to the following calendar year, of the volumes of transportation fuel, biomass-based diesel, and cellulosic biofuel projected to be sold or introduced into commerce in the United States.'' EIA provided these estimates to EPA on October 12, 2018.[57] With regard to liquid cellulosic biofuel, the EIA estimated that the available volume in 2019 would be 10 million gallons.

In its letter, EIA did not identify the facilities on which their estimate of liquid cellulosic biofuel production was based. EIA did, however, indicate in the letter that it only included domestic production of cellulosic ethanol in their projections. These projections, therefore, do not include cellulosic biofuel produced by foreign entities and imported into the U.S., nor estimates of cellulosic heating oil or CNG/LNG produced from biogas, which together represent approximately 98 percent of our projected cellulosic biofuel volume for 2019. When limiting the scope of our projection to the companies assessed by EIA, we note that our volume projections are equal. EPA projects approximately 10 million gallons of liquid cellulosic biofuel will be produced domestically in 2019, all of which is expected to be cellulosic ethanol.

D. Cellulosic Biofuel Volume for 2019

1. Liquid Cellulosic Biofuel

For our 2019 liquid cellulosic biofuel projection, we use the same general approach as we have in projecting these volumes in previous years. We begin by first categorizing potential liquid cellulosic biofuel producers in 2019 according to whether or not they have achieved consistent commercial scale production of cellulosic biofuel to date. We refer to these facilities as consistent producers and new producers, respectively. Next, we define a range of likely production volumes for 2019 for each group of companies. Finally, we use a percentile value to project from the established range a single projected production volume for each group of companies in 2019. As in 2018, we calculated percentile values for each group of companies based on the past performance of each group relative to our projected production ranges. This methodology is briefly described here, and is described in detail in memoranda to the docket.[58]

We first separate the list of potential producers of cellulosic biofuel (listed in Table III.B.3–1) into two groups according to whether the facilities have achieved consistent commercial-scale production and cellulosic biofuel RIN generation. We next defined a range of likely production volumes for each group of potential cellulosic biofuel producers. For the final rule, we have updated the companies included in our projection, the categorization of these companies, and the low and high end of the potential production range for each company for 2019 based on updated information. The low end of the range for each group of producers reflects actual RIN generation data over the last 12 months for which data are available at the time our technical assessment was completed (October 2017–September 2018).[59] For potential producers that have not yet generated any cellulosic RINs, the low end of the range is zero. For the high end of the range, we considered a variety of factors, including the expected start-up date and ramp-up period, facility capacity, and the number of RINs the producer expects to generate in 2019.[60] The projected range for each group of companies is shown in Tables III.D.1–1 and III.D.1–2 below.[61]

TABLE III.D.1–1—2019 PRODUCTION RANGES FOR LIQUID CELLULOSIC BIOFUEL PRODUCERS WITHOUT CONSISTENT COMMERCIAL SCALE PRODUCTION

[Million ethanol-equivalent gallons]

Companies included	Low end of the range	High end of the range [a]
Enerkem, Ensyn (Port Cartier facility)	0	10

[a] Rounded to the nearest million gallons.

[57] ''EIA letter to EPA with 2019 volume projections 10–12–18,'' available in docket EPA–HQ–OAR–2018–0167.

[58] ''November 2018 Liquid Cellulosic Biofuel Projections for 2018 CBI'' and ''Calculating the Percentile Values Used to Project Liquid Cellulosic Biofuel Production for the 2019 FRM,'' memorandums from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[59] Consistent with previous years, we have considered whether there is reason to believe any of the facilities considered as potential cellulosic biofuel producers for 2019 is likely to produce a smaller volume of cellulosic biofuel in 2019 than in the previous 12 months for which data are available. At this time, EPA is not aware of any information that would indicate lower production in 2019 from any facility considered than in the previous 12 months for which data are available.

[60] As in our 2015–2018 projections, EPA calculated a high end of the range for each facility (or group of facilities) based on the expected start-up date and a six-month straight line ramp-up period. The high end of the range for each facility (or group of facilities) is equal to the value calculated by EPA using this methodology, or the number of RINs the producer expects to generate in 2019, whichever is lower.

[61] More information on the data and methods EPA used to calculate each of the ranges in these tables in contained in ''November 2018 Liquid Cellulosic Biofuel Projections for 2018 CBI'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167. We have not shown the projected ranges for each individual company. This is because the high end of the range for some of these companies are based on the company's production projections, which they consider confidential business information (CBI). Additionally, the low end of the range for facilities that have achieved consistent commercial scale production is based on actual RIN generation data in the most recent 12 months, with is also claimed as CBI.

TABLE III.D.1–2—2019 PRODUCTION RANGES FOR LIQUID CELLULOSIC BIOFUEL PRODUCERS WITH CONSISTENT COMMERCIAL SCALE PRODUCTION

[Million ethanol-equivalent gallons]

Companies included	Low end of the range [a]	High end of the range [b]
Facilities using Edeniq's technology (registered facilities), Ensyn (Renfrew facility), Poet-DSM, GranBio, QCCP/Syngenta, Raizen	14	44

[a] Rounded to the nearest million gallons.

After defining likely production ranges for each group of companies, we next determined the percentile values to use in projecting a production volume for each group of companies. In this final rule we have calculated the percentile values using actual production data from January 2016 through September 2018 (the last month for which actual data is available) and projected production data for the remaining months of 2018 (October—December 2018). This approach is consistent with the approach taken in the 2018 final rule.

For each group of companies and for each year from 2016—2018, Table III.D.1–3 below shows the projected ranges for liquid cellulosic biofuel production (from the 2014–16, 2017, and 2018 final rules), actual production, and the percentile values that would have resulted in a projection equal to the actual production volume.

TABLE III.D.1–3—PROJECTED AND ACTUAL LIQUID CELLULOSIC BIOFUEL PRODUCTION IN 2016–2018

[Million gallons]

	Low end of the range	High end of the range	Actual production [62]	Actual percentile
New Producers: [63]				
2016	0	76	1.06	1st
2017	0	33	8.79	27th
2018	0	47	4.16	9th
Average [a]	N/A	N/A	N/A	12th
Consistent Producers: [64]				
2016	2	5	3.28	43rd
2017	3.5	7	3.02	−14th
2018	7	24	9.86	17th
Average [a]	N/A	N/A	N/A	15th

[a] We have not averaged the low and high ends of the ranges, or actual production, as we believe it is more appropriate to average the actual percentiles from 2016–2018 rather than calculating a percentile value for 2016–2018 in aggregate. This approach gives equal weight to the accuracy of our projections from 2016–2018, rather than allowing the average percentiles calculated to be dominated by years with greater projected volumes.

Based upon the above analysis, EPA has projected cellulosic biofuel production from new producers at the 12th percentile of the calculated range and from consistent producers at the 15th percentile.[65] These percentiles are calculated by averaging the percentiles that would have produced cellulosic biofuel projections equal to the volumes produced by each group of companies in 2016–2018. Prior to 2016, EPA used different methodologies to project available volumes of cellulosic biofuel, and thus believes it inappropriate to calculate percentile values based on projections from those years.[66]

EPA also considered whether or not to include the percentile value from 2016 in our calculation of the percentile value to use in projecting liquid cellulosic biofuel production in 2019. Including a larger number of years in our calculation of the percentile value for 2019 would result in a larger data set that is less susceptible to large fluctuations that result from unexpectedly high or low production volumes in any one year that may not be indicative of future production. However, including a larger number of years also necessarily requires including older data that may no longer reflect the likely production of liquid cellulosic biofuel in a future year, especially given the rapidly changing nature of this industry.

We ultimately decided to include data from 2016 in calculating the percentile values to project liquid cellulosic biofuel production in 2019, determining that there was significant value in including this additional data. Even though the liquid cellulosic biofuel industry has changed since 2016, these changes are not so significant as to render this data obsolete. In determining the percentile values to use for 2019 we have also decided to weight the observed actual percentile values from 2016–2018 equally. While the percentile

[62] Actual production is calculated by subtracting RINs retired for any reason other than compliance with the RFS standards from the total number of cellulosic RINs generated.

[63] Companies characterized as new producers in the 2014–2016, 2017, and 2018 final rules were as follows: Abengoa (2016), CoolPlanet (2016), DuPont (2016, 2017), Edeniq (2016, 2017), Enerkem (2018), Ensyn Port Cartier (2018), GranBio (2016, 2017), IneosBio (2016), and Poet (2016, 2017).

[64] Companies characterized as consistent producers in the 2014–2016, 2017, and 2018 final rules were as follows: Edeniq Active Facilities (2018), Ensyn Renfrew (2016–2018), GranBio (2018), Poet (2018), and Quad County Corn Processors/Syngenta (2016–2018).

[65] For more detail on the calculation of the percentile values used in this final rule see ''Calculating the Percentile Values Used to Project Liquid Cellulosic Biofuel Production for 2018 and 2019,'' available in EPA docket EPA–HQ–OAR–2018–0167.

[66] EPA used a similar projection methodology for 2015 as in 2016–2018, however we only projected cellulosic biofuel production volume for the final 3 months of the year, as actual production data were available for the first 9 months. We do not believe it is appropriate to consider data from a year for which 9 months of the data were known at the time the projection was made in determining the percentile values used to project volume over a full year.

value from 2018 represents the most recent data available, it is also dependent on the performance of a relatively small number of companies in a single year, as well as a projection of the performance of these facilities during the final three months of 2018. Using data from multiple years, especially years in which we have complete production data, is likely more representative of the future performance of these groups of companies than data from any single year.

Commenters generally supported EPA's use of updated data (data not available at the time of the proposed rule, but expected to be available for the final rule) in calculating the percentage standards for 2019. Several commenters objected to EPA's use of a single percentile value based on historical production performance for each group of companies. These commenters often described this approach as ''backwards looking'' and generally requested that EPA not discount facility's projected production at all, determine a unique percentile value for each facility based on facility specific factors, or return to the percentile values used in the 2016 and 2017 rules (25th percentile for new producers and 50th percentile for consistent producers).

EPA disagrees with the commenters characterization of the projection methodology used in this final rule as ''backwards looking.'' As discussed above, and in more detail in a memorandum to the docket,[67] EPA has used data specific to 2019 in determining the high end of the potential production range for these facilities. While we acknowledge that we have relied on data from previous years in calculating the percentile value we use to select a volume within the potential production range for each group of companies, we believe that this approach is appropriate and consistent with EPA's direction to project cellulosic biofuel volumes with a neutral aim at accuracy. We do not believe that we have significant data or expertise to individually consider all of the potential variables associated with each individual facility and produce a reasonably accurate projection. Indeed, in the early years of the RFS program (2010–2013) EPA attempted this approach with very poor results. Similarly, using the 25th and 50th percentiles to project potential production produced overly optimistic projections in both 2016 (0.5 million gallons actual production versus 2 million gallons projected production) and 2017 (4.1 million actual, 12 million projected). By contrast, the approach used in the 2018 rule, which is also the approach used in this action, produced a much more precise estimate (14 million actual, 14 million projected). We believe the approach used today is likely to produce a more accurate projection of liquid cellulosic biofuel production.[68] This approach is therefore appropriate for projecting liquid cellulosic biofuel production in 2019. As this approach incorporates new data each year, we anticipate that we will be able to use it consistently in future years. However, as in previous years, EPA will continue to monitor the success of this approach going forward and will make adjustments to increase accuracy as necessary.

Finally, we used these percentile values, together with the ranges determined for each group of companies discussed above, to project a volume for each group of companies in 2019. These calculations are summarized in Table III.D.1–4 below.

TABLE III.D.1–4—PROJECTED VOLUME OF LIQUID CELLULOSIC BIOFUEL IN 2019

[Million ethanol-equivalent gallons]

	Low end of the range [a]	High end of the range [a]	Percentile	Projected volume [a]
Liquid Cellulosic Biofuel Producers; Producers without Consistent Commercial Scale Production	0	10	12th	1
Liquid Cellulosic Biofuel Producers; Producers with Consistent Commercial Scale Production	14	44	15th	19
Total	N/A	N/A	N/A	20

[a] Volumes rounded to the nearest million gallons.

2. CNG/LNG Derived From Biogas

For 2019, EPA is using the same methodology as in the 2018 final rule, an industry wide projection based on a year-over-year growth rate, to project production of CNG/LNG derived from biogas used as transportation fuel.[69] For this final rule, EPA has calculated the year-over-year growth rate in CNG/LNG derived from biogas by comparing RIN generation from October 2017 to September 2018 (the most recent 12 months for which data are available) to RIN generation in the 12 months that immediately precede this time period (October 2016 to September 2017). These RIN generation volumes are shown in Table III.D.2–1 below.

TABLE III.D.2–1—GENERATION OF CELLULOSIC BIOFUEL RINS FOR CNG/LNG DERIVED FROM BIOGAS

[Million gallons] [70]

RIN generation (October 2016–September 2017)	RIN generation (October 2017–September 2018)	Year-over-year increase
216	278	29.0%

[67] ''November 2018 Liquid Cellulosic Biofuel Projections for 2018 CBI,'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[68] The comments discussed in this paragraph are discussed in additional detail in Section 3.2.1 of the RTC document.

[69] Historically RIN generation for CNG/LNG derived from biogas has increased each year. It is possible, however, that RIN generation for these fuels in the most recent 12 months for which data are available could be lower than the preceding 12 months. We believe our methodology accounts for this possibility. In such a case, the calculated rate of growth would be negative.

[70] Further detail on the data used to calculate each of these numbers in this table, as well as the projected volume of CNG/LNG derived from biogas used as transportation fuel in 2019 can be found in ''November 2018 Assessment of Cellulosic Biofuel Production from Biogas (2019)'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

EPA then applied this 29 percent year-over-year growth rate to the total number of 2017 cellulosic RINs generated and available for compliance for CNG/LNG. This methodology results in a projection of 399 million gallons of CNG/LNG derived from biogas in 2019.[71] We believe that projecting the production of CNG/LNG derived from biogas in this manner appropriately takes into consideration the actual recent rate of growth of this industry, and that this growth rate accounts for both the potential for future growth and the challenges associated with increasing RIN generation from these fuels in future years. This methodology may not be appropriate to use as the projected volume of CNG/LNG derived from biogas approaches the total volume of CNG/LNG that is used as transportation fuel, as RINs can be generated only for CNG/LNG used as transportation fuel. We do not believe that this is yet a constraint as our projection for 2019 is well below the total volume of CNG/LNG that is currently used as transportation fuel.[72]

EPA has also reviewed data on potential producers of CNG/LNG derived from biogas that is used as transportation fuel. Compared to EPA, these potential producers projected greater total production of CNG/LNG derived from biogas in 2019 based on the capacity of such projects. Since producers of CNG/LNG derived from biogas have historically over-estimated their production of these fuels, it would not be appropriate to simply adopt the capacity of these projects as our projection of CNG/LNG derived from biogas for 2019. The fact that the industry projections exceed EPA's projected volume, however, indicates that the volume of these fuels projected for 2019 can be satisfied by a combination of projects currently producing CNG/LNG derived from biogas for these purposes and projects expected to product biogas by the end of 2019.

A number of commenters requested that, in addition to projecting volume of CNG/LNG derived from biogas using a year-over-year growth rate, EPA project additional volume to account for new projects and those currently in development. We believe that the industry-wide projection methodology used in this final rule already adequately accounts for new facilities and those currently in development. The growth rate used to project the production of CNG/LNG derived from biogas in 2019 includes both increased production from existing facilities, as well as new facilities that began producing fuel in the last 12 months for which data are available. Thus, adding additional volume to account for new facilities would effectively be double counting production from new facilities.

Other commenters suggested that the industry wide projection was inappropriate, and that EPA should return to a facility-by-facility assessment, as was used to project CNG/LNG derived from biogas in 2016 and 2017. We believe that the mature nature of the industry producing CNG/LNG derived from biogas lends itself well to an industry-wide projection methodology and that this methodology can be more accurate than a facility-by-facility approach, especially as macro market and economic factors have apparently become more influential on total production than the success or challenges at any single facility; especially as producers are vying for business relationships with the same pool of CNG/LNG fueled transportation fleets to enable them to generate RINs. We further note that the facility-by-facility approach used to project production of CNG/LNG produced from biogas in 2016 and 2017 significantly over-estimated production of these fuels.

While our projection methodology uses a growth rate based on historical data it adequately anticipates higher production volumes in future years, including both increased production from existing facilities as well as production from new facilities. In this way it satisfies our charge to project future cellulosic biofuel production in a reasonable manner, and with neutrality, even though it does not consider all potential producers of these fuels on a facility-by-facility basis.

3. Total Cellulosic Biofuel in 2019

After projecting production of cellulosic biofuel from liquid cellulosic biofuel production facilities and producers of CNG/LNG derived from biogas, EPA combined these projections to project total cellulosic biofuel production for 2019. These projections are shown in Table III.D.3–1. Using the methodologies described in this section, we project that 418 million ethanol-equivalent gallons of cellulosic biofuel will be produced in 2019. We believe that projecting overall production in 2019 in the manner described above results in a neutral estimate (neither biased to produce a projection that is too high nor too low) of likely cellulosic biofuel production in 2019.

TABLE III.D.3–1—PROJECTED VOLUME OF CELLULOSIC BIOFUEL IN 2019

[Million gallons]

	Projected volume [a]
Liquid Cellulosic Biofuel Producers; Producers without Consistent Commercial Scale Production	1
Liquid Cellulosic Biofuel Producers; Producers with Consistent Commercial Scale Production	19
CNG/LNG Derived from Biogas	399
Total	[b] 418

[a] Volumes rounded to the nearest million gallons.
[b] Total projection of cellulosic biofuel appears less than the sum of the projected volume for each group of companies due to rounding.

[71] To calculate this value, EPA multiplied the number of 2017 RINs generated and available for compliance for CNG/LNG derived from biogas (239.5 million), by 1.290 (representing a 29 percent year-over-year increase) to project production of CNG/LNG in 2018, and multiplied this number (309 million RINs) by 1.290 again to project production of CNG/LNG in 2019.

[72] EPA projects that 538 million ethanol-equivalent gallons of CNG/LNG will be used as transportation fuel in 2019 based on EIA's October 2018 Short Term Energy Outlook (STEO). To calculate this estimate, EPA used the Natural Gas Vehicle Use from the STEO Custom Table Builder (0.12 billion cubic feet/day in 2019). This projection includes all CNG/LNG used as transportation fuel from both renewable and non-renewable sources. EIA does not project the amount of CNG/LNG from biogas used as transportation fuel. To convert billion cubic feet/day to ethanol-equivalent gallons EPA used conversion factors of 946.5 British Thermal Units (BTU) per cubic foot of natural gas (lower heating value, per calculations using ASTM D1945 and D3588) and 77,000 BTU of natural gas per ethanol-equivalent gallon per 40 CFR 80.1415(b)(5).

Further discussion of the companies expected to produce cellulosic biofuel and make it commercially available in 2019 can be found in a memorandum to the docket.[73]

IV. Advanced Biofuel and Total Renewable Fuel Volumes for 2019

The national volume targets for advanced biofuel and total renewable fuel to be used under the RFS program each year through 2022 are specified in CAA section 211(o)(2)(B)(i)(I) and (II). Congress set annual renewable fuel volume targets that envisioned growth at a pace that far exceeded historical growth and, for years after 2011, prioritized that growth as occurring principally in advanced biofuels (contrary to previous growth patterns where most growth was in conventional renewable fuel). Congressional intent is evident in the fact that the implied statutory volume requirement for conventional renewable fuel is 15 billion gallons for all years after 2014, while the advanced biofuel volume requirements, driven largely by growth in cellulosic biofuel, continue to grow each year through 2022 to a total of 21 billion gallons.

Due to a shortfall in the availability of cellulosic and advanced biofuel, and consistent with our long-held interpretation of the cellulosic waiver authority as best interpreted and applied by providing equal reductions in advanced biofuel and total renewable fuel, we are reducing the statutory volume targets for both advanced biofuel and total renewable fuel for 2019 using the full extent of the cellulosic waiver authority.

In this Section we discuss our use of the discretion afforded by the cellulosic waiver authority at CAA 211(o)(7)(D)(i) to reduce volumes of advanced biofuel and total renewable fuel. We first discuss our assessment of advanced biofuel and the considerations that have led us to conclude that the advanced biofuel volume target in the statute should be reduced by the full amount permitted under the cellulosic waiver authority. We then address total renewable fuel in the context of our interpretation, articulated in previous annual rulemakings, that advanced biofuel and total renewable fuel should be reduced by the same amount under the cellulosic waiver authority. We also address several comments we received in response to the July 10, 2018 proposal; the remaining comments are addressed in a separate RTC document.

To begin, we have evaluated the capabilities of the market and are making a finding that the 13.0 billion gallons specified in the statute for advanced biofuel cannot be reached in 2019. This is primarily due to the expected continued shortfall in cellulosic biofuel; production of this fuel type has consistently fallen short of the statutory targets by 95 percent or more, and as described in Section III, we project that it will fall far short of the statutory target of 8.5 billion gallons in 2019. For this and other reasons described in this section we are reducing the advanced biofuel statutory target by the full amount of the shortfall in cellulosic biofuel for 2019.

In previous years when we have used the cellulosic waiver authority, we have determined the extent to which we should reduce advanced biofuel volumes by taking into account the availability of advanced biofuels, their energy security and greenhouse gas (GHG) impacts, the availability of carryover RINs, the apparent intent of Congress as reflected in the statutory volumes tables to substantially increase the use of advanced biofuels over time, as well as factors such as increased costs associated with the use of advanced biofuels and the increasing likelihood of adverse unintended impacts associated with use of advanced biofuel volumes achieved through diversion of foreign fuels or substitution of advanced feedstocks from other uses to biofuel production. Until the 2018 standards rule, the consideration of these factors led us to conclude that it was appropriate to set the advanced biofuel standard in a manner that would allow the partial backfilling of missing cellulosic volumes with non-cellulosic advanced biofuels.[74] For the 2018 standards, we placed a greater emphasis on cost considerations in the context of balancing the various considerations, ultimately concluding that partial backfilling with non-cellulosic advanced biofuels was not warranted and the applicable volume requirement for advanced biofuel should be based on the maximum reduction permitted under the cellulosic waiver authority.

Although we continue to believe that the factors earlier considered in exercising the cellulosic waiver authority are relevant and appropriate, we project that there will be insufficient reasonably attainable volumes of non-cellulosic advanced biofuels in 2019 to allow any backfilling for missing volumes of cellulosic biofuel.[75] As a result of this projection, the high cost of advanced biofuels, and our consideration of carryover RINs, we are reducing the statutory volume target for advanced biofuel by the same amount as the reduction in cellulosic biofuel. This will result in the non-cellulosic component of the advanced biofuel volume requirement being equal to the implied statutory volume target of 4.5 billion gallons in 2019.

Several stakeholders commented that it was inappropriate for EPA to change its policy with regard to backfilling of missing cellulosic biofuel with other advanced biofuel as it had done prior to 2018. However, in making such comments, stakeholders misinterpreted our approach in those years. While we permitted some backfilling, we did so only after considering such factors as described above. The approach we have taken for the 2019 volume requirements is no different than it was in previous years, though the outcome of that approach is different due to the different circumstances.

We note that the predominant non-cellulosic advanced biofuels available in the near term are advanced biodiesel and renewable diesel.[76] We expect limited growth in the availability of feedstocks used to produce these fuel types, absent the diversion of these feedstocks from other uses. In addition, we expect diminishing incremental GHG benefits and higher per gallon costs as the required volumes of advanced biodiesel and renewable diesel increase. These outcomes are a result of the fact that the lowest cost and most easily available feedstocks are typically used first, and each additional increment of advanced biodiesel and renewable diesel requires the use of feedstocks that are generally incrementally more costly and/or more difficult to obtain. Moreover, to the extent that higher advanced biofuel requirements cannot be satisfied through growth in the production of advanced biofuel feedstocks, they would instead be satisfied through a re-direction of such feedstocks from competing uses. Products (other than qualifying advanced biofuels) that were

[73] ''Cellulosic Biofuel Producer Company Descriptions (November 2018),'' memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[74] For instance, see 81 FR 89750 (December 12, 2016).

[75] As described further below, ''reasonably attainable'' volumes are not merely those that can be attained given available biofuel production capacity and feedstocks, but also take into consideration factors such as costs and feedstock and/or fuel diversions that could create disruptions in other markets.

[76] While sugarcane ethanol, as well as a number of other fuel types, can also contribute to the supply of advanced biofuel, in recent years supply of these other advanced biofuels has been considerably lower than supply of advanced biodiesel or renewable diesel. See Table IV.B.3–1.

formerly produced using these feedstocks are likely to be replaced by products produced using the lowest cost alternatives, likely derived from palm oil (for food and animal feed) or petroleum sources (non-edible consumer products). This in turn could increase the lifecycle GHG emissions associated with these incremental volumes of non-cellulosic advanced biofuel, since fuels produced from both palm oil and petroleum have higher estimated lifecycle GHG emissions than qualifying advanced biodiesel and renewable diesel.[77] There would also likely be market disruptions and increased burden associated with shifting feedstocks among the wide range of companies that are relying on them today and which have optimized their processes to use them. Higher advanced biofuel standards could also be satisfied by diversion of foreign advanced biofuel from foreign markets, and there would also be an increased likelihood of adverse unintended impacts associated with such diversions. Taking these considerations into account, we believe, as discussed in more detail below, that it is appropriate to exercise our discretion under the cellulosic waiver authority to set the advanced biofuel volume requirement at a level that would minimize such diversions.

Furthermore, several other factors have added uncertainty regarding the volume of advanced biofuels that we project are attainable in 2019. The first is the fact that the tax credit for biodiesel has not been renewed for 2019. The second is the final determination by the Department of Commerce that tariffs should be imposed on biodiesel imports from Argentina and Indonesia, and the potential for those tariffs to increase.[78] [79] Finally, China has recently imposed new tariffs on soybean imports. Each of these factors is discussed in more detail in Section IV.B.3 below.

We believe that the factors and considerations noted above are all appropriate to consider under the broad discretion provided under the cellulosic waiver authority, and that consideration of these factors supports our use of this authority. Many of the considerations discussed in this final rule are related to the availability of non-cellulosic advanced biofuels (*e.g.,* historic data on domestic supply, expiration of the biodiesel blenders' tax credit, potential imports of biodiesel in light of the Commerce Department's determination on tariffs on biodiesel imports from Argentina and Indonesia, potential imports of sugarcane ethanol, and anticipated decreasing growth in production of feedstocks for advanced biodiesel and renewable diesel), while others focus on the potential benefits and costs of requiring use of available volumes (*e.g.,* relative cost of advanced biofuels in comparison to the petroleum fuels they displace, GHG reduction benefits, and energy security benefits).

As discussed in further detail in the following sections, our assessment of advanced biofuel suggests that achieving the implied statutory volume target for non-cellulosic advanced biofuel in 2019 (4.5 billion gallons) is attainable. While it may also be possible that a volume of non-cellulosic advanced biofuel greater than 4.5 billion gallons may be attainable, a volume equal to or higher than 4.5 billion gallons would likely result in the diversion of advanced feedstocks from other uses or diversion of advanced biofuels from foreign sources, and thus is not reasonably attainable. In that case, our assessment of other factors, such as cost and GHG impacts, indicate that while such higher volumes may be attainable, it would not be appropriate to set the advanced biofuel volume requirement so as to require use of such volumes to partially backfill for missing cellulosic volumes.

The impact of our exercise of the cellulosic waiver authority is that after waiving the cellulosic biofuel volume down to the projected available level, and applying the same volume reduction to the statutory volume target for advanced biofuel, the resulting volume requirement for advanced biofuel for 2019 would be 630 million gallons more than the applicable volume used to derive the 2018 percentage standard. Furthermore, after applying the same reduction to the statutory volume target for total renewable fuel, the volume requirement for total renewable fuel would also be 630 million gallons more than the applicable volume used to derive the 2018 percentage standard.

A. Volumetric Limitation on Use of the Cellulosic Waiver Authority

As described in Section II.A, when making reductions in advanced biofuel and total renewable fuel under the cellulosic waiver authority, the statute limits those reductions to no more than the reduction in cellulosic biofuel. As described in Section III.D, we are establishing a 2019 applicable volume for cellulosic biofuel of 418 million gallons, representing a reduction of 8,082 million gallons from the statutory target of 8,500 million gallons. As a result, 8,082 million gallons is the maximum volume reduction for advanced biofuel and total renewable fuel that is permissible using the cellulosic waiver authority. Use of the cellulosic waiver authority to this maximum extent would result in volumes of 4.92 and 19.92 billion gallons for advanced biofuel and total renewable fuel, respectively.

TABLE IV.A–1—LOWEST PERMISSIBLE VOLUMES USING ONLY THE CELLULOSIC WAIVER AUTHORITY

[Million gallons]

	Advanced biofuel	Total renewable fuel
Statutory target	13,000	28,000
Maximum reduction permitted under the cellulosic waiver authority	8,082	8,082
Lowest 2019 volume requirement permitted using only the cellulosic waiver authority	4,918	19,918

We are authorized under the cellulosic waiver authority to reduce the advanced biofuel and total renewable fuel volumes ''by the same or a lesser'' amount as the reduction in the cellulosic biofuel volume.[80] As discussed in Section II.A, EPA has broad discretion in using the cellulosic

[77] For instance, see the draft GHG assessment of palm oil biodiesel and renewable diesel at 77 FR 4300 (January 27, 2012).

[78] ''Affirmative Final Antidumping Duty Determinations on Biodiesel From Argentina and Indonesia,'' available in docket EPA–HQ–OAR–2018–0167.

[79] ''US adds more duties on biodiesel from Argentina & Indonesia,'' Reuters article available in docket EPA–HQ–OAR–2018–0167.

waiver authority in instances where its use is authorized under the statute, since Congress did not specify factors that EPA must consider in determining whether to use the authority to reduce advanced biofuel or total renewable fuel, nor what the appropriate volume reductions (within the range permitted by statute) should be. This broad discretion was affirmed in both *Monroe* and *ACE*.[81] Thus, we have the authority set the 2019 advanced biofuel volume requirement at a level that is designed to partially backfill for the shortfall in cellulosic biofuel. However, based on our consideration of a number of relevant factors, we are using the full extent of the cellulosic waiver authority in deriving volume requirements for 2019.

B. Attainable Volumes of Advanced Biofuel

We have considered both attainable and reasonably attainable volumes of advanced biofuel to inform our exercise of the cellulosic waiver authority. As used in this rulemaking, both ''reasonably attainable'' and ''attainable'' are terms of art defined by EPA.[82] Volumes described as ''reasonably attainable'' are those that can be reached with minimal market disruptions, increased costs, and/or reduced GHG benefits, and with minimal diversion of advanced biofuels or advanced biofuel feedstocks from existing uses. We use this phrase in today's action in the same way that we used it in previous actions. Volumes described as ''attainable,'' in contrast, are those we believe can be reached, but would likely result in market disruption, higher costs, and/or reduced GHG benefits. Neither ''reasonably attainable'' nor ''attainable'' are meant to convey the ''maximum achievable'' level, which as we explained in the 2017 final rule, we do not consider to be an appropriate target under the cellulosic waiver authority.[83] Finally, we note that our assessments of the ''reasonably attainable'' and ''attainable'' volumes of non-cellulosic advanced biofuels are not intended to be as exacting as our projection of cellulosic biofuel production, described in Section III of this rule.

As in prior rulemakings, we begin by considering what volumes of advanced biofuels are reasonably attainable. In *ACE,* the Court noted that in assessing what volumes are ''reasonably attainable,'' EPA had considered the availability of feedstocks, domestic production capacity, imports, and market capacity to produce, distribute, and consume renewable fuel.[84] These considerations include both demand-side and supply-side factors.[85] We are taking a similar approach for 2019, with the added consideration of the possibility that higher volume requirements would lead to ''feedstock switching'' or diversion of advanced biofuels from use in other countries. We also took these factors into account in setting the 2017 and 2018 volume requirements, and we continue to believe that they are appropriate considerations under the broad discretion provided by the cellulosic waiver authority. We are establishing the advanced biofuel volume requirement at a level that would seek to minimize such feedstock/fuel diversions within the discretion available under the cellulosic waiver authority.

Our individual assessments of reasonably attainable volumes of each type of advanced biofuel reflect this approach. As discussed in further detail in this section, we find that 100 million gallons of advanced ethanol, 60 million gallons of other advanced biofuels, and 2.61 billion gallons of advanced biodiesel and renewable diesel are reasonably attainable. Together with our projected volume of 418 million gallons of cellulosic biofuel, the sum of these volumes falls short of 4.92 billion gallons, which is the lowest advanced biofuel requirement that EPA can require under the cellulosic waiver authority.

Therefore, we also have considered whether the market can nonetheless make available 4.92 billion gallons of advanced biofuel, notwithstanding likely feedstock/fuel diversions. That is, we assess whether 4.92 billion gallons is merely ''attainable,'' as opposed to reasonably attainable. In particular, we assess whether additional volumes of advanced biodiesel and renewable diesel are attainable. We conclude that 2.8 billion gallons of advanced biodiesel and renewable diesel are attainable, notwithstanding potential feedstock/fuel diversions. This quantity of advanced biodiesel and renewable diesel, together with the cellulosic biofuel, sugarcane ethanol, and other advanced biofuels described above, would enable the market to make available 4.92 billion gallons of advanced biofuels.

1. Imported Sugarcane Ethanol

The predominant available source of advanced biofuel other than cellulosic biofuel and BBD is imported sugarcane ethanol. Imported sugarcane ethanol from Brazil is the predominant form of imported ethanol and the only significant source of imported advanced ethanol. In setting the 2018 standards, we estimated that 100 million gallons of imported sugarcane ethanol would be reasonably attainable.[86] This was a reduction from the 200 million gallons we had assumed for 2016 and 2017, and was based on a combination of data from 2016 and part of 2017 as well as an attempt to balance the lower-than-expected imports from recent data with indications that higher volumes were possible based on older data. We also noted the high variability in ethanol import volumes in the past (including of Brazilian sugarcane ethanol), increasing gasoline consumption in Brazil, and variability in Brazilian production of sugar as reasons that it would be inappropriate to assume that sugarcane ethanol imports would reach the much higher levels suggested by some stakeholders.

Since the 2018 final rule, new data reveals a continued trend of low imports. At the time of the 2018 standards final rule, we had used available data from a portion of 2017 to estimate that import volumes of sugarcane ethanol were likely to fall significantly below the 200 million gallons we had assumed when we set the 2017 standards. Import data for all of 2017 is now available, and indicates that imports of sugarcane ethanol reached just 77 million gallons. Moreover, EIA data on monthly ethanol imports in 2018 through July indicate that no ethanol was imported.[87]

[80] CAA section 211(o)(7)(D)(i).

[81] See *ACE,* 864 F.3d at 730–35 (citing *Monroe,* 750 F.3d 909, 915–16).

[82] Our consideration of ''reasonably attainable'' volumes is not intended to imply that ''attainable'' volumes are unreasonable or otherwise inappropriate. As we explain in this section, we believe that an advanced biofuel volume of 4.92 billion gallons, although not reasonably attainable, is attainable, and that establishing such volume is an appropriate exercise of our cellulosic waiver authority.

[83] 81 FR 89762 (December 12, 2016). The maximum achievable volume may be relevant to our consideration of whether to exercise the general waiver authority on the basis of inadequate domestic supply. In 2019, we have determined that the after exercising our cellulosic waiver authority the advanced biofuel volume is achievable, and therefore further reductions using the general waiver authority on the basis of inadequate domestic supply are not necessary.

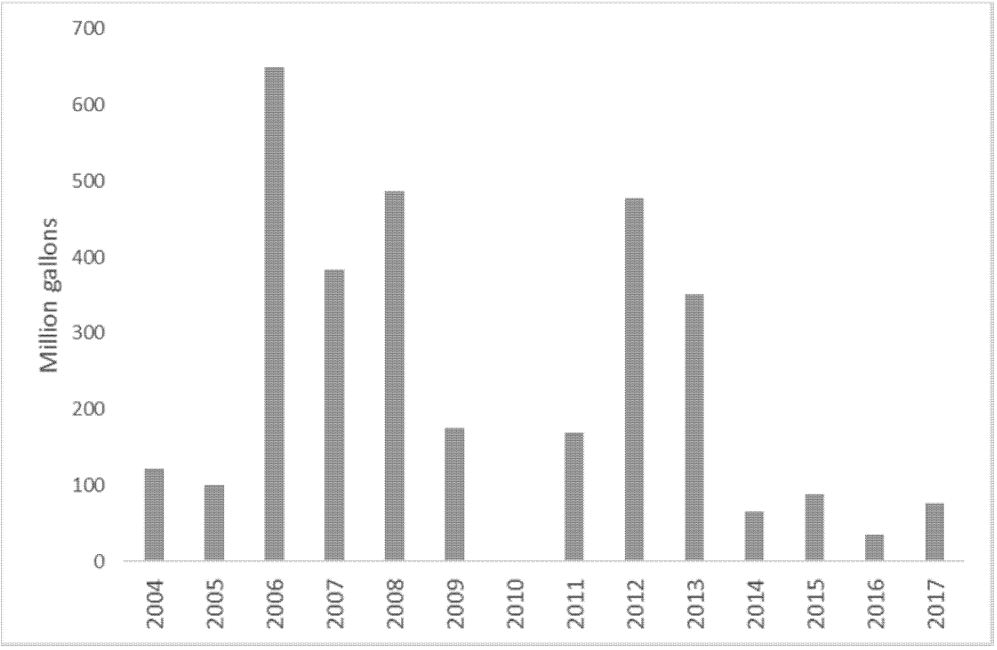
[84] See *ACE,* 864 F.3d at 735–36.

[85] See id. at 730–35.

[86] 82 FR 58507 (December 12, 2017).

[87] However, EIA data on weekly imports of ethanol does indicate that some ethanol was imported in August and October of 2018, totaling 37 million gallons. This volume was not reflected in the monthly EIA data as of September 28, 2018.

Figure IV.B.1-1
Historical Sugarcane Ethanol Imports



Source: "US Imports of Fuel Ethanol from EIA," docket EPA-HQ-OAR-2018-0167. Includes imports directly from Brazil and those that are transmitted through the Caribbean Basin Initiative and Central America Free Trade Agreement (CAFTA).

While it is difficult to predict imports for 2019, we believe it would be reasonable not to increase the assumed volume above 100 million gallons for purposes of determining whether an advanced biofuel volume requirement of 4.92 billion gallons is reasonably attainable for 2019. Although the advanced biofuel volume requirement for 2019 is about 630 million gallons higher than that for 2018, creating some incentive for increases in imports, we note that an even larger increase in the required volume of advanced biofuel between 2016 and 2017 was accompanied by only a very small increase in imports of sugarcane ethanol, from 34 million gallons in 2016 to 77 million gallons in 2017. Moreover, the E10 blendwall and the fact that imported sugarcane ethanol typically costs more than corn ethanol create disincentives for increasing imports above the levels in recent years, though the difference in RIN values between conventional and advanced ethanol may offset the cost difference to some degree.[88] Even so, we do not believe it would be appropriate to reduce the volume of imported sugarcane ethanol below 100 million gallons for the purposes of determining the 2019 volume requirement for advanced biofuel because imports have typically been higher in the second half of the year compared to the first half of the year, and have reached considerably more than 100 million gallons in the past.[89] Taking all of these considerations into account, we are using 100 million gallons of imported sugarcane ethanol for the purposes of projecting reasonably attainable volumes of advanced biofuel for 2019.[90] This level reflects a balancing of the information available to EPA at this time; both the lower import volumes that have occurred more recently with the higher volumes that are possible based on earlier years and under the influence of the higher standards in 2019. Additional discussion on this topic can be found in the RTC document.

We note that the future projection of imports of sugarcane ethanol is inherently imprecise, and that actual imports in 2019 could be lower or higher than 100 million gallons. Factors that could affect import volumes include uncertainty in the Brazilian political climate, weather and harvests in Brazil, world ethanol demand and prices, constraints associated with the E10 blendwall in the U.S., world demand for and prices of sugar, and the cost of sugarcane ethanol relative to that of corn ethanol. After considering these factors, and in light of the high degree of variability in historical imports of sugarcane ethanol, we believe that 100 million gallons is reasonably attainable for 2019.

2. Other Advanced Biofuel

In addition to cellulosic biofuel, imported sugarcane ethanol, and advanced biodiesel and renewable diesel, there are other advanced biofuels that can be counted in the determination of reasonably attainable volumes of advanced biofuel for 2019. These other advanced biofuels include non-cellulosic CNG, naphtha, heating oil, and domestically-produced advanced ethanol. However, the supply of these fuels has been relatively low in the last several years.

[88] For example, see the relative costs of imported sugarcane ethanol and corn ethanol in Tables V.D–2 and V.D–3 in the final rulemaking that established the 2017 standards (81 FR 89746, December 12, 2016).

[89] ''US Imports of Fuel Ethanol from EIA,'' available in docket EPA–HQ–OAR–2018–0167.

[90] We note that even if sugarcane ethanol imports fall below our projection of 100 million gallons in 2019, the advanced biofuel volume would still be achievable. For example, if sugarcane ethanol imports were only 50 million gallons in 2019, the market could still supply 4.5 billion gallons of non-cellulosic advanced biofuel by supplying an additional 33 million gallons of advanced biodiesel.

TABLE IV.B.2–1—HISTORICAL SUPPLY OF OTHER ADVANCED BIOFUELS

[Million ethanol-equivalent gallons]

	CNG/LNG	Heating oil	Naphtha	Domestic ethanol	Total [a]
2013	26	0	3	23	52
2014	20	0	18	26	64
2015	0	1	24	25	50
2016	0	2	26	27	55
2017	2	2	32	26	62

[a] Excludes consideration of D5 renewable diesel, as this category of renewable fuel is considered as part of BBD in Section IV.B.3 below.

The downward trend over time in CNG/LNG from biogas as advanced biofuel with a D code of 5 is due to the re-categorization in 2014 of landfill biogas from advanced (D code 5) to cellulosic (D code 3).[91] Total supply of these other advanced biofuels has exhibited no consistent trend during 2013 to 2017. Based on data from EMTS for these same categories of biofuel in 2018 through August, we estimate that total RIN generation in 2018 will be approximately the same as in 2017.[92] Based on this historical record, we believe that 60 million gallons is reasonably attainable in 2019.

We recognize that the potential exists for additional volumes of advanced biofuel from sources such as jet fuel, liquefied petroleum gas (LPG), butanol, and liquefied natural gas (as distinct from CNG), as well as non-cellulosic CNG from biogas produced in digesters. However, since they have been produced, if at all, in only de minimis and sporadic amounts in the past, we do not have a reasonable basis for projecting substantial volumes from these sources in 2019.[93]

3. Biodiesel and Renewable Diesel

Having projected the production volume of cellulosic biofuel, and the reasonably attainable volumes of imported sugarcane ethanol and ''other'' advanced biofuels, we next assess the potential supply of advanced biodiesel and renewable diesel. First, we calculate the amount of advanced biodiesel and renewable diesel that would need to be supplied to meet the advanced requirement were we to exercise our maximum discretion under the cellulosic authority: 2.8 billion gallons. This calculation, shown in Table IV.B.3–1 below, helps inform the exercise of our waiver authorities. Second, we consider the historical supply of these fuels and the impact of the biodiesel tax policy on advanced biodiesel and renewable diesel use in the U.S. Next, we consider factors that could potentially limit the supply of advanced biodiesel including the production capacity of advanced biodiesel and renewable diesel production facilities, the ability for the market to distribute and use these fuels, the availability of feedstocks to produce these fuels, and fuel imports and exports. Based on our projection of the domestic growth in advanced biodiesel and renewable diesel feedstocks we project a reasonably attainable volume of 2.61 billion gallons of advanced biodiesel and renewable diesel in 2019. Since this volume is lower than the 2.8 billion gallons we calculated would need to be supplied to meet the advanced requirement were we to exercise our maximum discretion under the cellulosic authority, we finally consider if additional supplies of advanced biodiesel and renewable diesel are attainable. Ultimately, we conclude that a volume of at least 2.8 billion gallons of advanced biodiesel and renewable diesel is attainable in 2019. We note that we have not attempted to determine the maximum attainable volume of these fuels. While the maximum attainable volume of advanced biodiesel and renewable diesel in 2019 is greater than 2.8 billion gallons we do not believe it would be appropriate to require a greater volume of these fuels (by establishing a higher advanced biofuel volume for 2019) due to the high cost and the increased likelihood of adverse unintended impacts associated with these fuels.

Calculating the volume of advanced biodiesel and renewable diesel that would be needed to meet the volume of advanced biofuel for 2019 is an important benchmark to help inform EPA's consideration of our waiver authorities. In situations where the reasonably attainable volume of biodiesel and renewable diesel exceeds the volume of these fuels that would be needed to meet the volume of advanced biofuel after reducing the advanced biofuel volume by the same amount as the cellulosic biofuel volume, as was the case in 2017 and 2018, EPA may consider whether or not to allow additional volumes of these fuels to backfill for missing cellulosic biofuel volumes. In situations where the reasonably attainable volume of advanced biodiesel and renewable diesel is less than the volume of these fuels that would be needed to meet the volume of advanced biofuel after reducing the advanced biofuel volume by the same amount as the cellulosic biofuel volume, EPA may consider whether or not to use additional waiver authorities, to the extent available, to make further reductions to the advanced biofuel volume.

[91] 79 FR 42128 (July 18, 2014).

[92] See ''Projecting Advanced Biofuel Production and Imports for 2018 (November 2018)'' Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[93] No RIN-generating volumes of these other advanced biofuels were produced in 2017, and less than 1 million gallons total in prior years.

TABLE IV.B.3–1—DETERMINATION OF VOLUME OF BIODIESEL AND RENEWABLE DIESEL NEEDED IN 2019 TO ACHIEVE 4.92 BILLION GALLONS OF ADVANCED BIOFUEL

[Million ethanol-equivalent gallons except as noted]

Lowest 2019 advanced biofuel volume requirement permitted using under the cellulosic waiver authority	4,918
Cellulosic biofuel	418
Imported sugarcane ethanol	100
Other advanced	60
Calculated advanced biodiesel and renewable diesel needed (ethanol-equivalent gallons/physical gallons)[94]	4,340/2,800

Having calculated the volume of advanced biodiesel and renewable diesel that would need to be supplied to meet the volume of advanced biofuel for 2019 after reducing the advanced biofuel volume by the same amount as the cellulosic biofuel volume, EPA next projected the reasonably attainable volume of these fuels for 2019. With regard to advanced biodiesel and renewable diesel, there are many different factors that could potentially influence the reasonably attainable volume of these fuels used as transportation fuel or heating oil in the U.S. These factors include the availability of qualifying biodiesel and renewable diesel feedstocks, the production capacity of biodiesel and renewable diesel facilities (both in the U.S. and internationally), and the availability of imported volumes of these fuels.[95] A review of the volumes of advanced biodiesel and renewable diesel used in previous years is especially useful in projecting the potential for growth in the production and use of such fuels, since for these fuels there are a number of complex and inter-related factors beyond simply the total production capacity for biodiesel and renewable diesel (including the availability of advanced feedstocks, the expiration of the biodiesel tax credit, recent tariffs on biodiesel from Argentina and Indonesia, and other market-based factors) that are likely to affect the supply of advanced biodiesel and renewable diesel.

In addition to a review of the volumes of advanced biodiesel and renewable diesel used in previous years, we believe the likely growth in production of feedstocks used to produce these fuels, as well as the total projected available volumes of these feedstocks, are important factors to consider. This is because while there are many factors that could potentially limit the production and availability of these fuels, the impacts of increasing production of advanced biodiesel and renewable diesel on factors such as costs, energy security, and GHG emissions are expected to vary depending on whether the feedstocks used to produce these fuels are sourced from waste sources or by-products of other industries (such as the production of livestock feed or ethanol production), are sourced from increased oilseed production, or are sourced from the diversion of feedstocks from existing uses. The energy security and GHG reduction value associated with the growth in the use of advanced biofuels is greater when these fuels are produced from waste fats and oils or feedstocks that are byproducts of other industries (such as soybean oil from soybeans primarily grown as animal feed), rather than a switching of existing advanced feedstocks from other uses to renewable fuel production or the diversion of advanced biodiesel and renewable diesel from foreign markets. This is especially true if the parties that previously used the advanced biofuel or feedstocks replace these oils with low cost palm oil[96] or petroleum derived products, as we believe would likely be the case in 2019.[97] In this case the global production of advanced biodiesel and renewable diesel would not increase, and the potential benefits associated with increasing the diversity of the supply of transportation fuel (energy security) and the production of additional volumes of advanced biodiesel and renewable diesel (low GHG sources of transportation fuel) would be reduced.

Before considering the projected growth in the production of qualifying feedstocks that could be used to produce advanced biodiesel and renewable diesel, as well as the total volume of feedstocks that could be used to produce these fuels, it is helpful to review the volumes of biodiesel and renewable diesel that have been used in the U.S. in recent years. While historic data and trends alone are insufficient to project the volumes of biodiesel and renewable diesel that could be provided in future years, historic data can serve as a useful reference in considering future volumes. Past experience suggests that a high percentage of the biodiesel and renewable diesel used in the U.S. (from both domestic production and imports) qualifies as advanced biofuel.[98] In previous years, biodiesel and renewable diesel produced in the U.S. have been almost exclusively advanced biofuel.[99] Imports of advanced biodiesel increased through 2016, but were lower in 2017 and 2018, as seen in Table IV.B.2–1. Volumes of imported advanced biodiesel and renewable diesel have varied significantly from year to year, as they are impacted both by domestic and foreign policies, as well as many economic factors.

[94] To calculate the volume of advanced biodiesel and renewable diesel that would generate the 4.34 billion RINs needed to meet the advanced biofuel volume EPA divided the 4.34 billion RINs by 1.55. 1.55 is the approximate average (weighted by the volume of these fuels expected to be produced in 2019) of the equivalence values for biodiesel (generally 1.5) and renewable diesel (generally 1.7).

[95] Throughout this section we refer to advanced biodiesel and renewable diesel as well as advanced biodiesel and renewable diesel feedstocks. In this context, advanced biodiesel and renewable diesel refer to any biodiesel or renewable diesel for which RINs can be generated that satisfy an obligated party's advanced biofuel obligation (*i.e.,* D4 or D5 RINs). While cellulosic diesel (D7) also contributed towards an obligated party's advanced biofuel obligation, these fuels are discussed in Section III rather than in this section. An advanced biodiesel or renewable feedstock refers to any of the biodiesel, renewable diesel, jet fuel, and heating oil feedstocks listed in Table 1 to 40 CFR 80.1426 or in petition approvals issued pursuant to section 80.1416, that can be used to produce fuel that qualifies for D4 or D5 RINs. These feedstocks include, for example, soy bean oil; oil from annual cover crops; oil from algae grown photosynthetically; biogenic waste oils/fats/greases; non-food grade corn oil; camelina sativa oil; and canola/rapeseed oil (See pathways F, G, and H of Table 1 to section 80.1426).

[96] For instance, see the draft GHG assessment of palm oil biodiesel and renewable diesel at 77 FR 4300 (January 27, 2012).

[97] We believe palm or petroleum derived products would likely be used replace advanced biodiesel and renewable diesel diverted to the U.S. as these products are currently the lowest cost sources.

[98] From 2011 through 2017 approximately 95 percent of all biodiesel and renewable diesel supplied to the U.S. (including domestically-produced and imported biodiesel and renewable diesel) qualified as advanced biodiesel and renewable diesel (11,701 million gallons of the 12,323 million gallons) according to EMTS data.

[99] From 2011 through 2017 over 99.9 percent of all the domestically produced biodiesel and renewable diesel supplied to the U.S. qualified as advanced biodiesel and renewable diesel (10,089 million gallons of the 10,096 million gallons) according to EMTS data.

TABLE IV.B.3–2—ADVANCED (D4 AND D5) BIODIESEL AND RENEWABLE DIESEL FROM 2011 TO 2017
[Million gallons] [a]

	2011	2012	2013	2014 [b]	2015 [b]	2016	2017	2018 [c]
Domestic Biodiesel (Annual Change)	967 (N/A)	1,014 (+47)	1,376 (+362)	1,303 (−73)	1,253 (−50)	1,633 (+380)	1,573 (−60)	1,896 (+323)
Domestic Renewable Diesel (Annual Change)	58 (N/A)	11 (−47)	92 (+81)	155 (+63)	175 (+20)	221 (+46)	258 (+37)	255 (−3)
Imported Biodiesel (Annual Change)	44 (N/A)	40 (−4)	156 (+116)	130 (−26)	261 (+131)	561 (+300)	462 (−99)	212 (−250)
Imported Renewable Diesel (Annual Change)	0 (N/A)	28 (+28)	145 (+117)	129 (−16)	121 (−8)	170 (+49)	193 (+23)	197 (+4)
Exported Biodiesel and Renewable Diesel (Annual Change)	48 (N/A)	102 (+54)	125 (+23)	134 (+9)	133 (−1)	129 (−4)	157 (+28)	103 (−54)
Total (Annual Change)	1,021 (N/A)	991 (−30)	1,644 (+653)	1,583 (−61)	1,677 (+94)	2,456 (+779)	2,329 (−127)	2,457 (+128)

[a] All data from EMTS. EPA reviewed all advanced biodiesel and renewable diesel RINs retired for reasons other than demonstrating compliance with the RFS standards and subtracted these RINs from the RIN generation totals for each category in the table above to calculate the volume in each year.
[b] RFS required volumes for these years were not established until December 2015.
[c] Data for 2018 is based on actual production and import data through September 2018, and a projection for October–December 2018. For more information on how the volumes for 2018 were determined see ''Projecting Advanced Biofuel Production and Imports for 2018 (November 2018)'' Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

TABLE IV.B.3–3—CONVENTIONAL (D6) BIODIESEL AND RENEWABLE DIESEL FROM 2011 TO 2017
[Million gallons] [a]

	2011	2012	2013	2014 [b]	2015 [b]	2016	2017	2018 [c]
Domestic Biodiesel (Annual Change)	0 (N/A)	0 (+0)	6 (+6)	1 (−5)	0 (+0)	0 (+0)	0 (+0)	0 (+0)
Domestic Renewable Diesel (Annual Change)	0 (N/A)	0 (+0)	0 (+0)	0 (+0)	0 (+0)	0 (+0)	0 (+0)	0 (+0)
Imported Biodiesel (Annual Change)	0 (N/A)	0 (+0)	31 (+31)	52 (+21)	74 (+22)	113 (+39)	0 (−113)	0 (+0)
Imported Renewable Diesel (Annual Change)	0 (N/A)	0 (+0)	53 (+53)	0 (−53)	106 (+106)	43 (−63)	144 (+101)	123 (−21)
Exported Biodiesel and Renewable Diesel (Annual Change)	0 (N/A)	0 (+0)	0 (+0)	0 (+0)	0 (+0)	1 (+1)	0 (−1)	0 (+0)
Total (Annual Change)	0 (N/A)	0 (+0)	90 (+90)	53 (−37)	180 (+127)	155 (−25)	144 (−11)	123 (−21)

[a] All data from EMTS. EPA reviewed all conventional biodiesel and renewable diesel RINs retired for reasons other than demonstrating compliance with the RFS standards and subtracted these RINs from the RIN generation totals for each category in the table above to calculate the volume in each year.
[b] RFS required volumes for these years were not established until December 2015.
[c] Data for 2018 is based on actual production and import data through September 2018, and a projection for October–December 2018. For more information on how the volumes for 2018 were determined see ''Projecting Biodiesel and Renewable Diesel Production and Imports for 2018 (November 2018)'' Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

Since 2011, the year-over-year changes in the volume of advanced biodiesel and renewable diesel used in the U.S. have varied greatly, from a low of 127 million fewer gallons from 2016 to 2017 to a high of 779 million additional gallons from 2015 to 2016. These changes were likely influenced by multiple factors such as the cost of biodiesel feedstocks and petroleum diesel, the status of the biodiesel blenders tax credit, growth in marketing of biodiesel at high volume truck stops and centrally fueled fleet locations, demand for biodiesel and renewable diesel in other countries, biofuel policies in both the U.S. and foreign countries, and the volumes of renewable fuels (particularly advanced biofuels) required by the RFS. This historical information does not indicate that the maximum previously observed increase of 779 million gallons of advanced biodiesel and renewable diesel would be reasonable to expect from 2018 to 2019, nor does it indicate that the low (or negative) growth rates observed in other years would recur in 2019. Rather, these data illustrate both the magnitude of the changes in advanced biodiesel and renewable diesel in previous years and the significant variability in these changes.

The historic data indicates that the biodiesel tax policy in the U.S. can have a significant impact on the volume of biodiesel and renewable diesel used in the U.S. in any given year.[100] While the biodiesel blenders tax credit has applied in each year from 2010 to 2017, it has only been prospectively in effect during the calendar year in 2011, 2013 and 2016, while other years it has been applied retroactively. The biodiesel blenders tax credit expired at the end of 2009 and was re-instated in December 2010 to apply retroactively in 2010 and extend through the end of 2011. Similarly, after expiring at the end of 2011, 2013, and 2014 the tax credit was re-instated in January 2013 (for 2012 and 2013), December 2014 (for 2014), December 2015 (for 2015 and 2016), and February 2018 (for 2017). Each of the years in which the biodiesel blenders tax credit was in effect during the calendar year (2013 and 2016) resulted in significant increases in the volume of advanced biodiesel and renewable diesel used in the U.S. over the previous year (653 million gallons and 779 million gallons respectively). However, following these large increases in 2013 and 2016, there was little to no growth in the use of advanced biodiesel and renewable diesel in the following years, only 33 million gallons from 2013 to 2015 and negative 127 million gallons from 2016 to 2017. This decrease from 2016 to 2017 occurred even though the required volume of advanced biofuel increased from 3.61 in 2016 to 4.28 billion gallons in 2017. This pattern is likely the result of both accelerated production and/or importation of biodiesel and renewable diesel in the final few months of years during which the tax credit was available to take advantage of the expiring tax credit, as well as relatively lower volumes of biodiesel and renewable diesel production and import in 2014, 2015,

[100] The status of the tax credit does not impact our assessment of the reasonably attainable volume of advanced biodiesel and renewable diesel in 2019 as our assessment is primarily based on feedstock availability. The status of the tax credit may affect the maximum attainable volume of these fuels, but our assessment demonstrates that 2.8 billion gallons of advanced biodiesel and renewable diesel is attainable whether or not the tax credit is renewed prospectively (or retrospectively) for 2019.

and 2017 than would have occurred if the tax credit had been in place.[101]

Some commenters stated that the tax credit has no impact on the potential supply of advanced biodiesel and renewable diesel. They generally argued that while the tax credit impacted the cost of biodiesel, as well as the RIN price needed to make advanced biodiesel and renewable diesel cost competitive with petroleum diesel, the RIN price was ultimately capable of incentivizing the production and use of advanced biodiesel and renewable diesel with or without the tax credit. We recognize that this is theoretically true; because the RIN prices vary with the supply and demand for RINs, the RIN price can rise to provide the same value as the tax credit in its absence. However, we note that it is this very aspect of the price of RINs, the potential that RIN prices may rise or fall depending on market conditions, that can hinder their ability to incentivize increased production and use of advanced biodiesel and renewable diesel. Further, higher advanced biofuel RIN prices can incentivize the production of other advanced fuels if these fuels can be produced at a price that is cost competitive with advanced biodiesel and renewable diesel. Conversely, the tax credit provides a fixed price incentive for all biodiesel and renewable diesel blended into the diesel fuel pool in the U.S., and is not available to other advanced biofuels. Ultimately, as discussed above the supply of biodiesel and renewable diesel is likely to be influenced by a number of factors, including the 2019 RFS volume requirements, the advanced and BBD RIN prices, expectations about the availability of the biodiesel blenders tax credit, and a number of other market-based factors.

The historical data suggests that the supply of advanced biodiesel and renewable diesel could potentially increase from the projected 2.54 billion gallons in 2018 to 2.8 billion gallons in 2019 (the projected volume needed to meet the advanced biofuel volume for 2019 after reducing the statutory advanced biofuel volume by the same amount as the cellulosic biofuel reduction). This would represent an increase of approximately 250 million gallons from 2018 to 2019, slightly higher than the average increase in the volume of advanced biodiesel and renewable diesel used in the U.S. from 2011 through 2017 (218 million gallons per year) and significantly less than the highest annual increase during this time (779 million gallons from 2015 to 2016).

After reviewing the historical volume of advanced biodiesel and renewable diesel used in the U.S. and considering the possible impact of the expiration of the biodiesel tax credit (discussed above), EPA next considers other factors that may impact the production, import, and use of advanced biodiesel and renewable diesel in 2019. The production capacity of registered advanced biodiesel and renewable diesel production facilities is highly unlikely to limit the production of these fuels, as the total production capacity for biodiesel and renewable diesel at registered facilities in the U.S. (4.1 billion gallons) exceeds the volume of these fuels that are projected to be needed to meet the advanced biofuel volume for 2019 after exercising the cellulosic waiver authority (2.8 billion gallons).[102] Significant registered production also exists internationally. Similarly, the ability for the market to distribute and use advanced biodiesel and renewable diesel appears unlikely constrain the growth of these fuels to a volume lower than 2.8 billion gallons. The investments required to distribute and use this volume of biodiesel and renewable diesel are expected to be modest, as this volume is less than 200 million gallons greater than the volume of biodiesel and renewable diesel produced, imported, and used in the U.S. in 2016.

Conversely, the availability of advanced feedstocks that can be used to produce advanced biodiesel and renewable diesel, as well as the availability of imported advanced biodiesel and renewable diesel, may be limited in 2019. We acknowledge that an increase in the required use of advanced biodiesel and renewable diesel could be realized through a diversion of advanced feedstocks from other uses, or a diversion of advanced biodiesel and renewable diesel from existing markets in other countries. Furthermore, the volume of advanced biodiesel and renewable diesel and their corresponding feedstocks projected to be produced globally exceeds the volume projected to be required in 2019 (2.8 billion gallons of advanced biodiesel and renewable diesel and the corresponding volume of advanced feedstocks) by a significant margin.[103] It is also the case that actions unrelated to the RFS program, such as recent tariffs on soybeans exported to China, could result in increased supplies of domestic biodiesel feedstocks.[104] However, we expect that further increases in advanced biofuel and renewable fuel volumes would be increasingly likely to incur adverse unintended impacts.

We perceive the net benefits to be lower both because of the potential disruption and associated cost impacts to other industries resulting from feedstock switching, and the potential adverse effect on lifecycle GHG emissions associated with feedstocks for biofuel production that would have been used for other purposes and which must then be backfilled with other feedstocks. Similarly, increasing the supply of biodiesel and renewable diesel to the U.S. by diverting fuel that would otherwise have been used in other countries results in higher lifecycle GHG emissions than if the supply of these fuels was increased by an increased collection of waste fats and oils or increased production of feedstocks that are byproducts of other industries, especially if this diversion results in increased consumption of petroleum fuels in the countries that would have otherwise consumed the biodiesel or renewable diesel. By focusing our assessment of the potential growth in the attainable volume of biodiesel and renewable diesel on the expected growth in the production of advanced feedstocks (rather than the total supply of these feedstocks in 2018, which would include feedstocks currently being used for non-biofuel purposes), we are attempting to minimize the incentives for the RFS program to increase the supply of advanced biodiesel and renewable diesel through feedstock switching or diverting biodiesel and renewable diesel from foreign markets to the U.S.

Advanced biodiesel and renewable diesel feedstocks include both waste oils, fats, and greases; and oils from planted crops. We received many comments from parties projecting that

[101] We also acknowledge that EPA not finalizing the required volumes of renewable fuel under the RFS program for 2014 and 2015 until December 2015 likely affected the volume of advanced biodiesel and renewable diesel supplied in these years. Further, the preliminary tariffs on biodiesel imported from Argentina and Indonesia announced in August 2017 likely negatively affected the volume of biodiesel supplied in 2017.

[102] The production capacity of the sub-set of biodiesel and renewable diesel producers that generated RINs in 2017 is approximately 3.1 billion gallons. See ''Biodiesel and Renewable Diesel Registered Capacity (May 2018)'' Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[103] The October 2018 WASDE projects production of vegetable oils in 2017/2018 in the World to be 203.33 million metric tons. This quantity of vegetable oil would be sufficient to produce approximately 58.1 billion gallons of biodiesel and renewable diesel. Global production of biodiesel is projected to be 38.0 billion liters (10.0 billion gallons) according to the 2018 OECD–FAO Agricultural Outlook.

[104] The potential impacts of this tariff on the availability of biodiesel feedstocks is discussed in our discussion of available vegetable oils below.

available feedstocks from both of these sources are expected to increase in 2019. We agree that increases in the availability of advanced feedstocks would in 2019 and we have projected the magnitude of these increases using the best available data, including data received in comments on this rule. The projected growth in advanced feedstocks, however, is expected to be modest relative to the volume of these feedstocks that are currently being used to produce biodiesel and renewable diesel. Most of the waste oils, fats, and greases that can be recovered economically are already being recovered and used in biodiesel and renewable diesel production or for other purposes. The availability of animal fats will likely increase with beef, pork, and poultry production. Most of the vegetable oil used to produce advanced biodiesel and renewable diesel that is sourced from planted crops comes from crops primarily grown for purposes other than providing feedstocks for biodiesel and renewable diesel, such as for livestock feed, with the oil that is used as feedstock for renewable fuel production a co-product or by-product.[105] This is true for soybeans and corn, which are the two largest sources of feedstock from planted crops used for biodiesel production in the U.S.[106] We do not believe that the increased demand for soybean oil or corn oil caused by a higher 2019 advanced biofuel standard would result in an increase in soybean or corn prices large enough to induce significant changes in agricultural activity.[107] However, we acknowledge that production of these feedstocks is likely to increase as crop yields, oil extraction rates, and demand for the primary products increase in 2019.

We believe the most reliable source for projecting the expected increase in vegetable oils in the U.S. is USDA's World Agricultural Supply and Demand Estimates (WASDE). At the time of our assessment for this final rule, the most current version of the WASDE is from October 2018. The projected increase in vegetable oil production in the U.S. from 2017/2018 to 2018/2019 is 0.14 million metric tons per year. This additional quantity of vegetable oils could be used to produce approximately 40 million additional gallons of advanced biodiesel or renewable diesel in 2019 relative to 2018.[108] We recognize that oilseed production is projected in increase by a much greater amount (6.89 million metric tons).[109] However, it is the vegetable oil, rather than oilseed production, that is of relevance as an advanced biodiesel and renewable diesel feedstock.

A number of commenters mentioned the tariffs recently enacted by China on soybean exports from the U.S. as a potential source of additional feedstock for advanced biodiesel and renewable diesel. The potential impacts of these tariffs are significant, as approximately 25 percent of the U.S. soybean crop is currently exported to China.[110] However, the duration and ultimate impacts of these tariffs on total exports of U.S. soybeans are highly uncertain. In recent months, the price premium for soybeans from Brazil (the largest global exporter of soybeans), which are not impacted by the tariffs, have increased to approximately $2 per bushel.[111] A likely result of this price premium is that countries other than China will turn to U.S. sources of soybeans, rather than sourcing soybeans from Brazil. Ultimately, the tariffs could have little impact on the overall exports of soybeans from the U.S.

The most recent WASDE report projects that exports of oilseeds will decrease by approximately 2 million metric tons (approximately 3 percent) from 2017/2018 to 2018/2019. In addition, the WASDE projects that exports of vegetable oils will decrease by 0.10 million metric tons during this same time period. The October WASDE appears to take the recent tariffs into account, as there is a notable decrease in the expected trade of oilseeds in the recent WASDE projections relative to WASDE projections made prior to the announcement of Chinese tariffs on U.S. soybeans.[112] If the 2 million metric tons of soybeans were crushed to produce vegetable oil, this oil, along with the 0.10 million metric ton decrease in vegetable oil exports, could be used to produce approximately 130 million gallons of biodiesel and renewable diesel, less than 6 percent of the current market.[113] We believe this is a reasonable estimate of the volume of biodiesel and renewable diesel that could be produced from a decrease in exports of oilseeds and vegetable oil from the U.S. in 2019. However, any biodiesel and renewable diesel produced from soybeans previously exported to China are necessarily diverted from other uses (even if the reason for this diversion is the tariffs, rather than the RFS program), and are therefore more likely to have the adverse unintended impacts associated with diverted feedstocks. We therefore have not included this potential volume increase in our assessment of the reasonably attainable volume of these fuels in 2019. These feedstocks are a likely source of additional supply of advanced biodiesel and renewable diesel that could contribute towards satisfying the difference between the reasonably attainable volume of these fuels and the 2.8 billion gallons of these fuels projected to be used to satisfy the advanced biofuel volume for 2019. We further note that even if the 130 million gallons of biodiesel and renewable diesel that could be produced from a

[105] For example, corn oil is a co-product of corn grown primarily for feed or ethanol production, while soy and canola are primarily grown as livestock feed.

[106] According to EIA data 6,230 million pounds of soy bean oil and 1,579 million pounds of corn oil were used to produce biodiesel in the U.S. in 2017. Other significant sources of feedstock were yellow grease (1,471 million pounds), canola oil (1,452 million pounds), and white grease (591 million pounds). Numbers from EIA's September 2018 Monthly Biodiesel Production Report.

[107] This position is supported by several commenters, including the South Dakota Soybean Association (EPA–HQ–OAR–2018–0167–0389), the International Council on Clean Transportation (EPA–HQ–OAR–2018–0167–0531), and the Union of Concerned Scientists (EPA–HQ–OAR–2018–0167–0535).

[108] To calculate this volume, we have used a conversion of 7.7 pounds of feedstock per gallon of biodiesel. This is based on the expected conversion of soybean oil (*http://extension.missouri.edu/p/G1990*), which is the largest source of feedstock used to produce advanced biodiesel and renewable diesel. Conversion rates for other types of vegetable oils used to produce biodiesel and renewable diesel are similar to those for soybean oil.

[109] *World Agricultural Supply and Demand Estimates.* United States Department of Agriculture. October 11, 2018.

[110] Hart, Chad and Schulz, Lee. *China's Importance in U.S. Ag Markets.* CARD Agricultural Policy Review. Available online: *https://www.card.iastate.edu/ag_policy_review/article/?a=41.*

[111] Durisin, Megan and Dodge, Sam. *Why Soybeans Are at the Heart of the U.S.-China Trade War.* Bloomberg. Published July 5, 2018. Updated July 9, 2018.

[112] Projected trade of oilseeds decreased from 63.46 million metric tons for 2018/2019 in the June 2018 WASDE report to 57.20 million metric tons for 2018/2019 in the October 2018 WASDE.

[113] To calculate the quantity of oil that can be produced from 2 million metric tons of oilseeds we converted this total to approximately 73 million bushels of soybeans, assuming 60 pounds per bushel. We then calculated that this quantity of soybeans could produce approximately 800 million pounds of oil assuming each bushel of soybeans produced 11 pounds of oil. To this, we added the approximately 220 million pounds (0.10 million metric tons) of decreased exports of vegetable oils for a total of 1.02 billion pounds of vegetable oils. Finally, we divided this total by 7.7 pounds of vegetable oil per gallon of biodiesel (or renewable diesel) to estimate that 130 million gallons of biodiesel and renewable diesel could be produced from these feedstocks. Support for the 7.7 pounds of vegetable oil per gallon of biodiesel conversion factor can be found here: *http://extension.missouri.edu/p/G1990. All other conversion factors are from* Irwin, S. ''The Value of Soybean Oil in the Soybean Crush: Further Evidence on the Impact of the U.S. Biodiesel Boom.'' *farmdoc daily* (7):169, Department of Agricultural and Consumer Economics, University of Illinois at Urbana-Champaign, September 14, 2017.

decrease in exports of oilseeds and vegetable oil from the U.S. in 2019 were included in our projection of the reasonably attainable volume of advanced biodiesel and renewable diesel, this projection would still be less than 2.8 billion gallons.

In addition to virgin vegetable oils, we also expect increasing volumes of distillers corn oil [114] to be available for use in 2019. The WASDE report does not project distillers corn oil production, so EPA must use an alternative source to project the growth in the production of this feedstock. For this final rule EPA is using results from the World Agricultural Economic and Environmental Services (WAEES) model to project the growth in the production of distillers corn oil.[115] In assessing the likely increase in the availability of distillers corn oil from 2018 to 2019, the authors of the WAEES model considered the impacts of an increasing adoption rate of distillers corn oil extraction technologies at domestic ethanol production facilities, as well as increased corn oil extraction rates enabled by advances in this technology. The WAEES model projects that production of distillers corn oil in 2018 will increase by approximately 120 million pounds from the 2017/2018 to the 2018/2019 agricultural marketing year. This quantity of feedstock could be used to produce approximately 15 million gallons of biodiesel or renewable diesel. We believe it is reasonable to use these estimates from the WAEES model for these purposes.

While much of the increase in advanced biodiesel and renewable diesel feedstocks produced in the U.S. from 2018 to 2019 is expected to come from virgin vegetable oils and distillers corn oil, increases in the supply of other sources of advanced biodiesel and renewable diesel feedstocks, such as biogenic waste oils, fats, and greases, may also occur. These increases, however, are expected to be modest, as many of these feedstocks that can be recovered economically are already being used to produce biodiesel or renewable diesel, or in other markets. In fact, the WAEES model projects an increase of only 5 million gallons in the volume of biodiesel produced from feedstocks other than soybean oil, canola oil, and distillers corn oil from 2018 to 2019.[116] Conversely, an assessment conducted by LMC in 2017 and submitted in comments on our proposed rule projected that the waste oil supply in the U.S. could increase by approximately 2.4 million metric tons from 2016 to 2022.[117] This estimate represents a growth rate of approximately 0.4 billion tons per year, or enough feedstock to produce approximately 115 million gallons of biodiesel and renewable diesel per year. This estimate, however, only accounts for potential sources of feedstock, and not for the economic viability of recovering waste oils. While we acknowledge that additional waste oils could be collected in 2019, these waste oils will only be collected if it is economically viable to do so. Neither the results of the WAEES model, nor the future prices of soybean oil,[118] suggest the prices for waste oils will increase to a level that will incentivize significantly more wasted oil collection in 2019 relative to previous years. We have therefore included an additional 5 million gallons of advanced biodiesel and renewable diesel from wasted oils in our assessment of the reasonably attainable volume for 2019, consistent with the results of the WAEES model.

In total, we expect that increases in feedstocks produced in the U.S. are sufficient to produce approximately 60 million more gallons of advanced biodiesel and renewable diesel in 2019 relative to 2018. This number includes 40 million gallons from increased vegetable oil production, 15 million gallons from increased corn oil production, and 5 million gallons from increased waste oil collection. This number does not include additional volumes related to decreases in exported volumes of soybeans to China as a result of tariffs and/or increased collection of waste oils. Decreased exports of soybeans and soybean oil, represent feedstocks diverted from use in other countries, while any increase in the collection of waste oils is highly uncertain. Our projection also does not consider factors which could potentially decrease the availability of advanced biofuel feedstocks that could be used to produce biodiesel or renewable diesel, such as an increase in the volume of vegetable oils used in food markets or other non-biofuel industries. In our 2018 final rule, we determined that 2.55 billion gallons of advanced biodiesel and renewable diesel were reasonably attainable in 2018,[119] therefore our projection of the reasonably attainable volume of advanced biodiesel and renewable diesel in 2019 is 2.61 billion gallons.

EPA's projections of the growth of advanced feedstocks does not, however, suggest that the total supply of advanced biodiesel and renewable diesel to the U.S. in 2018 will be limited to 2.61 billion gallons. Rather, this is the volume of these fuels that we project could be supplied while seeking to minimize quantities of advanced feedstocks or biofuels from existing uses. The October 2018 WASDE reports that production of vegetable oil in the U.S. in the 2018/2019 market year will be sufficient to produce approximately 3.5 billion gallons of biodiesel and renewable diesel (including both advanced and conventional biofuels) if the entire volume of vegetable oil was used to produce these fuels. Additional advanced biodiesel and renewable diesel could be produced from waste fats, oils, and greases. The global production of vegetable oil projected in the 2018/2019 marketing year would be sufficient to produce approximately 58.1 billion gallons of biodiesel and renewable diesel (including both advanced and conventional biofuels).[120] While it would not be reasonable to assume that all, or even a significant portion, of global vegetable oil production could be available to produce biodiesel or renewable diesel supplied to the U.S. for a number of reasons,[121] the large global supply of vegetable oil strongly suggests that under the right market conditions 2.8 billion gallons of advanced biodiesel and renewable diesel is attainable in 2019. Reaching these levels, however, may result in the diversion of advanced feedstocks currently used in other markets and/or the import of biodiesel and renewable diesel from these feedstocks.

Further, the supply of advanced biodiesel and renewable diesel to the U.S. in 2019 could be increased by

[114] Distillers corn oil is non-food grade corn oil produced by ethanol production facilities.

[115] For the purposes of this rule, EPA relied on WAEES modeling results submitted as comments by the National Biodiesel Board on the 2019 proposed rule (Kruse, J., ''Implications of an Alternative Advanced and Biomass Based Diesel Volume Obligation for Global Agriculture and Biofuels'', August 13, 2018, World Agricultural Economic and Environmental Services (WAEES)).

[116] Id.

[117] LMC International. *Global Waste Grease Supply.* August 2017.

[118] CME Group Soybean Oil Futures Quotes. Accessed online October 23, 2018.

[119] 82 FR 58512 (December 12, 2017).

[120] The October 2018 WASDE projects production of vegetable oils in 2018/19 in the U.S. and the World to be 12.27 and 203.33 million metric tons respectively. To convert projected vegetable oil production to potential biodiesel and renewable diesel production we have used a conversion of 7.7 pounds of feedstock per gallon of biodiesel.

[121] These reasons include the demand for vegetable oil in the food, feed, and industrial markets both domestically and globally; constraints related to the production, import, distribution, and use of significantly higher volumes of biodiesel and renewable diesel; and the fact that biodiesel and renewable diesel produced from much of the vegetable oil available globally would not qualify as an advanced biofuel under the RFS program.

approximately 150 million gallons if all of the exported volumes of these fuels were used domestically. Diverting this fuel to markets in the U.S. may be complicated, however, as doing so would likely require higher prices for these fuels in the U.S. (to divert the fuels from foreign markets that are presumably more profitable currently). It may also be more difficult and costly to distribute this additional volume of biodiesel and renewable diesel to domestic markets than the current foreign markets. Finally, reducing advanced biodiesel and renewable diesel exports may indirectly result in the decreased availability of imported volumes of these fuels, as other countries seek to replace volumes previously imported from the U.S.

EPA next considered potential changes in the imports of advanced biodiesel and renewable diesel produced in other countries. In previous years, significant volumes of foreign produced advanced biodiesel and renewable diesel have been supplied to markets in the U.S. (see Table IV.B.2–1 above). These significant imports were likely the result of a strong U.S. demand for advanced biodiesel and renewable diesel, supported by the RFS standards, the low carbon fuel standard (LCFS) in California, the biodiesel blenders tax credit, and the opportunity for imported biodiesel and renewable diesel to realize these incentives. As in 2018, we have not included the potential for increased volumes of imported advanced biodiesel and renewable diesel in our projection of the reasonably attainable volume for 2019. There is a far higher degree of uncertainty related to the availability and production of advanced biodiesel and renewable diesel in foreign countries, as this supply can be impacted by a number of unpredictable factors such as the imposition of tariffs and increased incentives for the use of these fuels in other countries (such as tax incentives or blend mandates). EPA also lacks the data necessary to determine the quantity of these fuels that would otherwise be produced and used in other countries, and thus the degree to which the RFS standards are simply diverting this fuel from use in other countries as opposed to incentivizing additional production.

The RFS requirements and California's LCFS are expected to continue to provide an incentive for imports of advanced biodiesel and renewable diesel in 2019. Several other factors, however, may negatively impact the volume of these fuels imported in 2019. In February 2018 the biodiesel blenders tax credit, which had expired at the end of 2016, was retroactively reinstated for biodiesel blended in 2017 but was not extended to apply to biodiesel blended in 2018 or 2019.[122] Perhaps more significantly, in December 2017 the U.S. International Trade Commission adopted tariffs on biodiesel imported from Argentina and Indonesia.[123] According to data from EIA,[124] no biodiesel was imported from Argentina or Indonesia since September 2017, after a preliminary decision to impose tariffs on biodiesel imported from these countries was announced in August 2017. Biodiesel imports from these countries were significant prior to the imposition of tariffs, accounting for over 550 million gallons in 2016 and approximately 290 million gallons in 2017.

Despite these tariffs, imports of biodiesel and renewable diesel have not ceased. From January to June 2018, biodiesel and renewable diesel imports (according to EIA data) are approximately 172 million gallons, suggesting an annual volume of approximately 390 million gallons if the current import rates and seasonal trends hold through the end of the year.[125] This suggests that imported volumes of advanced biodiesel and renewable diesel from countries other than Argentina and Indonesia may increase by approximately 100 million gallons in 2018 (from approximately 290 million gallons in 2017). However overall imports have not returned to the levels observed prior to the tariffs. At this time, the ultimate impact these tariffs will have on overall imports of advanced biodiesel and renewable diesel to the U.S. remains uncertain. It appears likely that imports of advanced biodiesel and renewable diesel from other countries not impacted by these tariffs will continue to increase, however these increases may not be sufficient to replace all of the biodiesel imported from Argentina and Indonesia in previous years by 2019.

In addition to EPA's assessment of the market's ability to produce, import, distribute, and use the 2.8 billion gallons of advanced biodiesel and renewable diesel projected to be used in 2019 to meet the advanced biofuel volume requirement, EPA compared the projected increase in these fuels to the increases observed in recent years. While each year's circumstances are unique, a projected increase comparable to pas increases further confirms that the volume is attainable. Domestic production of advanced biodiesel and renewable diesel in 2016 and 2017 was approximately 1.85 billion gallons, and is expected to increase to approximately 2.15 billion gallons in 2018 based on production data through September 2018. Of this total, approximately 150 million gallons of domestically produced biodiesel was exported in 2016 and 2017. If imported biodiesel and renewable diesel volumes continue to increase through 2019 by approximately 100 million gallons per year (to approximately 500 million gallons in 2019) domestic production would need to increase by approximately 300 million gallons in 2019 to reach a total advanced biodiesel and renewable diesel supply of 2.8 billion gallons by 2019.[126] This growth is attainable, as it is approximately equal to the increase in the domestic production of advanced biodiesel and renewable diesel from 2017 to 2018 (approximately 300 million gallons), and significantly lower than the rate of growth observed in previous years (for example the increase of 653 million gallons from 2012 to 2013 or the increase of 779 million gallons from 2015 to 2016). We note, however, that using this volume of advanced biodiesel and renewable diesel in the U.S. may result in the diversion of advanced biodiesel and renewable diesel and/or feedstocks used to produce these fuels, as advanced biodiesel and renewable diesel that is currently exported may instead be used in the U.S. and alternative sources for significant volumes of these fuels would need to be found.

After a careful consideration of the factors discussed above, EPA has determined that the 2.8 billion gallons of advanced biodiesel and renewable diesel projected needed to satisfy the implied statutory volume for non-cellulosic advanced biofuel in 2019 (4.5 billion gallons) are attainable. The total

[122] Bipartisan Budget Act of 2018, Public Law 115–123, 132 Stat. 64 sections 40406, 40407, and 40415 (2018).

[123] ''Biodiesel from Argentina and Indonesia Injures U.S. Industry, says USITC,'' Available online at: *https://www.usitc.gov/press_room/news_release/2017/er1205ll876.htm.*

[124] See ''U.S. Imports of Biodiesel'' available in docket EPA–HQ–OAR–2018–0167.

[125] See ''U.S. Imports of Biodiesel'' available in docket EPA–HQ–OAR–2018–0167 and ''Projecting Biodiesel and Renewable Diesel Production and Imports for 2018 (November 2018)'' Memorandum from Dallas Burkholder to EPA Docket EPA–HQ–OAR–2018–0167.

[126] This estimate assumes that the U.S. continues to export approximately 150 million gallons of biodiesel per year in 2019. Alternatively, if the U.S. consumes all domestically produced biodiesel and renewable diesel, rather than exporting any of this fuel, domestic production of advanced biodiesel and renewable diesel would have to increase by approximately 150 million gallons in 2019. This volume is approximately equal to the increase in the domestic production of advanced biodiesel and renewable diesel from 2018 to 2019, which we also believe is attainable.

production capacity of registered biodiesel and renewable diesel producers is significantly higher than 2.8 billion gallons, even if only those facilities that generated RINs for advanced biodiesel and renewable diesel in 2017 are considered (3.1 billion gallons). This volume (2.8 billion gallons) is only 200 million gallons higher than the total volume of biodiesel and renewable diesel supplied in 2016 (approximately 2.6 billion gallons), strongly suggesting that production capacity and the ability to distribute and use biodiesel and renewable diesel will not limit the supply of advanced biodiesel and renewable diesel to a volume below 2.8 billion gallons in 2018. Sufficient feedstocks are expected to be available to produce this volume of advanced biodiesel and renewable diesel in 2019, however doing so may result in some level of diversion of advanced feedstocks and/or advanced biodiesel and renewable diesel from existing uses. Finally, the increase in the production and import of advanced biodiesel and renewable diesel projected from 2018 to 2019 is comparable to (or has been exceeded) by the increases observed in recent years. While we do not believe it will be necessary, in the event that the supply of advanced biodiesel and renewable diesel falls short of the projected 2.8 billion gallons in 2019, obligated parties could rely on the significant volume of carryover advanced RINs projected to be available in 2019 (See Section II.B for a further discussion of carryover RINs).

C. Volume Requirement for Advanced Biofuel

In exercising the cellulosic waiver authority for 2017 and earlier, we determined it was appropriate to require a partial backfilling of missing cellulosic volumes with volumes of non-cellulosic advanced biofuel we determined to be reasonably attainable, notwithstanding the increase in costs associated with those decisions.[127] For the 2018 standards, in contrast, we placed a greater emphasis on cost considerations in the context of balancing the various considerations, ultimately concluding that the applicable volume requirement should be based on the maximum reduction permitted under the cellulosic waiver authority. For 2019 we concluded that while it may be possible that more than 4.92 billion gallons of advanced biofuel is attainable in 2019, requiring additional volumes would lead to higher costs, and would likely result in feedstock switching and/or diversion of foreign advanced biofuels.[128] We do not believe that it would be appropriate to set the advanced biofuel volume requirement higher than 4.92 billion gallons given that it could lead to these results.

We further note that while there is some uncertainty in the volume of advanced biofuel that may be attainable or reasonably attainable, even if greater volumes of advanced biofuel are attainable or reasonably attainable, the high cost of these fuels provides sufficient justification for our decision to reduce the advanced biofuel volume for 2019 by the maximum amount under the cellulosic waiver authority. In Section V we present illustrative cost projections for sugarcane ethanol and soybean biodiesel in 2019, the two advanced biofuels that would be most likely to provide the marginal increase in volumes of advanced biofuel in 2019 in comparison to 2018. Sugarcane ethanol results in a cost increase compared to gasoline that ranges from $0.39–$1.04 per ethanol-equivalent gallon. Soybean biodiesel results in a cost increase compared to diesel fuel that ranges from $0.74–$1.23 per ethanol-equivalent gallon. The cost of these renewable fuels is high as compared to the petroleum fuels they displace.

Based on the information presented above, we believe that 4.92 billion gallons of advanced biofuel is attainable in 2019. After a consideration of the projected volume of cellulosic biofuel and reasonably attainable volumes of imported sugarcane ethanol and other advanced biofuels, we determined that 2.8 billion gallons of advanced biodiesel and renewable diesel would be needed to reach 4.92 billion gallons of advanced biofuel. Based on a review of the factors relevant to the supply of advanced biodiesel and renewable diesel as discussed in Section IV.B.2 above, including historic production and import data, the production capacity of registered biodiesel and renewable diesel producers, and the availability of advanced feedstocks, we have determined that 2.8 billion gallons of advanced biodiesel and renewable diesel is attainable in 2019.

However, we also acknowledge that 2.8 billion gallons of advanced biodiesel and renewable diesel is higher than the approximately 2.5 billion gallons projected to be supplied in 2018 based on available data through September 2018. While 2.8 billion gallons would require an increase in supply of approximately 300 million gallons between 2018 and 2019, this is approximately equal to the increase in domestic production of these fuels from 2017 to 2018, and approximately 100 million gallons less than the increase in the supply of advanced biodiesel and renewable diesel between 2017 and 2018 after adjusting for imported volumes of these fuels from Argentina and Indonesia in 2017.[129] Nevertheless, there is some uncertainty regarding whether the market will actually supply 2.8 billion gallons in 2019.

In the event that the market does not supply this volume, the carryover RIN bank represents a source of RINs that could help obligated parties meet an advanced biofuel volume requirement of 4.92 billion gallons in 2019 if the market fails to supply sufficient advanced biofuels in 2019. As discussed in greater detail in Section II.B.1 of the preamble, carryover RINs provide obligated parties compliance flexibility in the face of substantial uncertainties in the transportation fuel marketplace, and provide a liquid and well-functioning RIN market upon which success of the entire program depends. We currently estimate that there are approximately 620 million advanced carryover RINs available.

In response to the proposal, we received comments supporting our proposed volume requirement of 4.92 billion gallons, as well as comments requesting higher or lower volumes. EPA's assessment of these comments is provided in the RTC document.

It should be noted that by exercising the full cellulosic waiver authority for advanced biofuel, the implied statutory volume target for non-cellulosic advanced biofuel of 4.5 billion gallons in 2019 would be maintained. This represents an increase of 0.5 billion gallons from the 2018 volume requirements.

[127] See, *e.g.,* Renewable Fuel Standards for 2014, 2015 and 2016, and the Biomass-Based Volume for 2017: Response to Comments (EPA–420–R–15–024, November 2015), pages 628–631, available in docket EPA–HQ–OAR–2015–0111–3671.

[128] There will likely be some feedstock switching and/or diversion of foreign advanced biofuels to achieve an advanced biofuel volume of 4.92 billion gallons. However, further reductions in the advanced biofuel volume requirement would require the use of the general waiver authority, which we do not believe is warranted.

[129] To calculate the increase in the supply of advanced biodiesel and renewable diesel between 2017 and 2018 after adjusting for imported volumes of these fuels from Argentina and Indonesia in 2017, we subtracted the volume of biodiesel imported from Argentina and Indonesia in 2017 from the total volume of these fuels supplied in 2017 and compared this volume of advanced biodiesel and renewable diesel supplied in 2018. There have been no imports of biodiesel from Argentina and Indonesia since August 2017, when tariffs on biodiesel imported from these countries were announced.

D. Volume Requirement for Total Renewable Fuel

As discussed in Section II.A.1, we believe that the cellulosic waiver provision is best interpreted to reduce the advanced biofuel and total renewable fuel volumes by equal amounts. For the reasons we have previously articulated, we believe this interpretation is consistent with the statutory language and best effectuates the objectives of the statute. If we were to reduce the total renewable fuel volume requirement by a lesser amount than the advanced biofuel volume requirement, we would effectively increase the opportunity for conventional biofuels to participate in the RFS program beyond the implied statutory volume of 15 billion gallons. Applying an equal reduction of 8.12 billion gallons to both the statutory target for advanced biofuel and the statutory target for total renewable fuel results in a total renewable fuel volume of 19.92 billion gallons as shown in Table IV.A–1.[130] This volume of total renewable fuel results in an implied volume of 15 billion gallons of conventional fuel, which is the same as in the 2018 final rule.

In response to the July 10, 2018 proposal, some stakeholders said that EPA had not evaluated whether 19.92 billion gallons of total renewable fuel was attainable as it did for advanced biofuel. As a result, they indicated that EPA had not fulfilled its responsibilities under the statute and had not given stakeholders meaningful opportunity to evaluate the proposed volume requirement. In response, we note first of all that we proposed, and are finalizing, the maximum reduction possible under the cellulosic waiver authority, and thus no additional reductions are possible under that authority. Secondly, while the general waiver authority does provide a means for further reductions in the applicable volume requirement for total renewable fuel, the record before us does not indicate that a waiver is warranted as described in Section II of the RTC.

Notwithstanding the fact that we did not propose to use, and in this final rule are not using the general waiver authority, we did in fact provide a description of the ways in which the market could make 19.92 billion gallons volume of total renewable fuel available in 2019 in a memorandum to the docket.[131] Some stakeholders pointed specifically to a lack of any analysis of the volumes of E0, E15, and E85 as a reason that the assessment in that memorandum was insufficient. However, the supply and use of these gasoline-ethanol blends is strongly influenced by consumer demand. We noted in the proposal that, regardless of the outcome of such an assessment, we were precluded from waiving volumes due to inadequate domestic supply insofar as our assessment depended on a consideration of demand-side factors.

More importantly, an analysis of the volumes of E0, E15, and E85 that could be supplied in 2019 was not necessary to determine whether the volume requirement of 19.92 billion gallons could be reached.[132] This is because it is the total volume of ethanol that can be consumed that is the relevant consideration in evaluating the reasonableness of 19.92 billion gallons, not the specific volumes of E0, E15, and E85.[133] To this end, we began with the assumption that the nationwide average ethanol concentration could reach 10.11 percent in 2019 because it had reached this same level in 2017. In the context of a market wherein nearly all gasoline contains 10 percent ethanol, the average ethanol concentration provides a better indication of the net effect of all E0, E15, and E85 without the need to estimate the volumes of each. In essence, our assumption that the average ethanol concentration would be at least 10.11 percent provided a surrogate for attempting to separately estimate volumes of E0, E15, and E85, which would contain a high degree of uncertainty. Thus, as a result our use of the average ethanol content is both more straightforward and more robust. In addition to a consideration of the volumes of non-ethanol renewable fuel that could be available in 2019, our consideration of 10.13 percent nationwide average ethanol concentration led us to a proposed determination that the market could make available 19.88 billion gallons of total renewable fuel in 2019. Following this same approach, the updated market impacts for this final rule similarly demonstrates that the market can make available 19.92 billion gallons of total renewable fuel in 2019.

V. Impacts of 2019 Volumes on Costs

In this section, EPA presents its assessment of the illustrative costs of the final 2019 RFS rule. It is important to note that these illustrative costs do not attempt to capture the full impacts of this final rule. We frame the analyses we have performed for this rule as ''illustrative'' so as not to give the impression of comprehensive estimates. These estimates are provided for the purpose of showing how the cost to produce a gallon of a ''representative'' renewable fuel compares to the cost of petroleum fuel. There are a significant number of caveats that must be considered when interpreting these illustrative cost estimates. For example, there are many different feedstocks that could be used to produce biofuels, and there is a significant amount of heterogeneity in the costs associated with these different feedstocks and fuels. Some renewable fuels may be cost competitive with the petroleum fuel they replace; however, we do not have cost data on every type of feedstock and every type of fuel. Therefore, we do not attempt to capture this range of potential costs in our illustrative estimates.

Illustrative cost estimates are provided below for this final rule. The volumes for which we have provided cost estimates and are described in Sections III and IV, and result from reducing the cellulosic, advanced, and total renewable fuel volume requirements using the cellulosic waiver authority under CAA section 211(o)(7)(D)(i). For this rule we examine two different cases. In the first case, we provide illustrative cost estimates by comparing the final 2019 renewable fuel volumes to 2019 statutory volumes. In the second case, we examine the final 2019 renewable fuel volumes to the final 2018 renewable fuel volumes to estimate changes in the annual costs of the final 2019 RFS volumes in comparison to the 2018 volumes.

[130] EPA also considered the availability of carryover RINs in determining whether reduced use of the cellulosic waiver authority would be warranted. For the reasons described in Section II.B, we do not believe this to be the case.

[131] ''Updated market impacts of biofuels in 2019,'' memorandum from David Korotney to docket EPA–HQ–OAR–2018–0167. In prior actions including the 2019 proposed rule and the 2018 annual rule proposal, similar analyses indicated that the market was capable of both producing and consuming the required volume of renewable fuels, and that as a result there was no basis for finding an inadequate domestic supply of total renewable fuel. See 82 FR 34229 & n.82 (July 21, 2017). Given the D.C. Circuit's decision in *ACE,* however, assessment of demand-side constraints is no longer relevant for determining inadequate domestic supply. However, we believe consideration of the ways that the market could make this volume available may still be generally relevant to whether and how EPA exercises its waiver authorities, such as our consideration of whether the volumes will cause severe economic harm.

[132] Cf. *API,* 706 F.3d at 481 (''Nothing in the text of § 7545(o)(7)(D)(i), or any other applicable provision of the Act, plainly requires EPA to support its decision not to reduce the applicable volume of advanced biofuels with specific numerical projections.'').

[133] Importantly, EPA is not requiring the use of any specific ethanol blend; rather, the market chooses which biofuels and blends to use to satisfy the biofuel standards. See 42 U.S.C. 7545(o)(2)(A)(iii)(II)(bb) (the RFS program ''shall not'' ''impose any per-gallon obligation for the use of renewable fuel'').

A. Illustrative Costs Analysis of Exercising the Cellulosic Waiver Authority Compared to the 2019 Statutory Volumes Baseline

In this section, EPA provides illustrative cost estimates that compare the final 2019 cellulosic biofuel volume requirements to the 2019 cellulosic statutory volume that would be required absent the exercise of our cellulosic waiver authority under CAA section 211(o)(7)(D)(i).[134] As described in Section III, we are finalizing a cellulosic volume of 418 million gallons for 2019, using our cellulosic waiver authority to waive the statutory cellulosic volume of 8.5 billion gallons by 8.082 billion gallons. Estimating the cost savings from volumes that are not projected to be produced is inherently challenging. EPA has taken the relatively straightforward methodology of multiplying this waived cellulosic volume by the wholesale per-gallon costs of cellulosic biofuel production relative to the petroleum fuels they displace.

While there may be growth in other cellulosic renewable fuel sources, we believe it is appropriate to use cellulosic ethanol produced from corn kernel fiber as the representative cellulosic renewable fuel. The majority of liquid cellulosic biofuel in 2019 is expected to be produced using this technology, and application of this technology in the future could result in significant incremental volumes of cellulosic biofuel. In addition, as explained in Section III, we believe that production of the major alternative cellulosic biofuel—CNG/LNG derived from biogas—is limited to approximately 538 million gallons due to a limitation in the number of vehicles capable of using this form of fuel.[135]

EPA uses a ''bottom-up'' engineering cost analysis to quantify the costs of producing a gallon of cellulosic ethanol derived from corn kernel fiber. There are multiple processes that could yield cellulosic ethanol from corn kernel fiber. EPA assumes a cellulosic ethanol production process that generates biofuel using distiller's grains, a co-product of generating corn starch ethanol that is commonly dried and sold into the feed market as distillers dried grains with solubles (DDGS), as the renewable biomass feedstock. We assume an enzymatic hydrolysis process with cellulosic enzymes to break down the cellulosic components of the distiller's grains. This process for generating cellulosic ethanol is similar to approaches currently used by industry to generate cellulosic ethanol at a commercial scale, and we believe these cost estimates are likely representative of the range of different technology options being developed to produce ethanol from corn kernel fiber. We then compare the per-gallon costs of the cellulosic ethanol to the petroleum fuels that would be replaced at the wholesale stage, since that is when the two are blended together.

These cost estimates do not consider taxes, retail margins, or other costs or transfers that occur at or after the point of blending (transfers are payments within society and are not additional costs). We do not attempt to estimate potential cost savings related to avoided infrastructure costs (*e.g.,* the cost savings of not having to provide pumps and storage tanks associated with higher-level ethanol blends). When estimating per-gallon costs, we consider the costs of gasoline on an energy-equivalent basis as compared to ethanol, since more ethanol gallons must be consumed to travel the same distance as on gasoline due to the ethanol's lower energy content.

Table V.A–1 below presents the cellulosic fuel cost savings with this final rule that are estimated using this approach.[136] The per-gallon cost difference estimates for cellulosic ethanol ranges from $0.27–$2.80 per ethanol-equivalent gallon.[137] Given that cellulosic ethanol production is just starting to become commercially available, the cost estimates have a significant range. Multiplying those per-gallon cost differences by the amount of cellulosic biofuel waived in this final rule results in approximately $2.2–$23 billion in cost savings.

TABLE V.A–1—ILLUSTRATIVE COSTS OF EXERCISING THE CELLULOSIC WAIVER AUTHORITY COMPARED TO THE 2019 STATUTORY VOLUMES BASELINE

Cellulosic Volume Required (Million Ethanol-Equivalent Gallons)	418
Change in Required Cellulosic Biofuel from 2019 Statutory Volume (Million Ethanol-Equivalent Gallons)	(8,082)
Cost Difference Between Cellulosic Corn Kernel Fiber Ethanol and Gasoline Per Gallon ($/Ethanol-Equivalent Gallons) [138]	$0.27–$2.80
Annual Change in Overall Costs (Million $) [139]	$(2,200)–$(23,000)

B. Illustrative Costs of the 2019 Volumes Compared to the 2018 RFS Volumes Baseline

In this section, we provide illustrative cost estimates for EPA exercising its cellulosic waiver authority to reduce statutory cellulosic volumes for 2019 (with corresponding reductions to the advanced and total renewable fuel volumes) compared to the final 2018 RFS volumes. This results in an increase in cellulosic volumes for the 2019 RFS of 130 gallons (ethanol-equivalent) and an increase in the non-cellulosic advanced biofuel volumes for 2019 of 500 million gallons (ethanol-equivalent).

1. Cellulosic Biofuel

We anticipate that the increase in the final 2019 cellulosic biofuel volumes would be composed of 5 million gallons of liquid cellulosic biofuel and 125

[134] Since the implied non-cellulosic advanced biofuel and implied conventional renewable fuel volumes are unchanged from the statutory implied volumes, see supra note, there is no need to estimate cost impacts for these volumes.

[135] EPA projects that 538 million ethanol-equivalent gallons of CNG/LNG will be used as transportation fuel in 2019 based on EIA's October 2018 Short Term Energy Outlook (STEO). To calculate this estimate, EPA used the Natural Gas Vehicle Use from the STEO Custom Table Builder (0.12 billion cubic feet/day in 2019). This projection includes all CNG/LNG used as transportation fuel from both renewable and non-renewable sources. EIA does not project the amount of CNG/LNG from biogas used as transportation fuel. To convert billion cubic feet/day to ethanol-equivalent gallons EPA used conversion factors of 946.5 BTU per cubic foot of natural gas (lower heating value, per calculations using ASTM D1945 and D3588) and 77,000 BTU of natural gas per ethanol-equivalent gallon per 40 CFR 80.1415(b)(5).

[136] Details of the data and assumptions used can be found in a Memorandum available in the docket entitled ''Cost Impacts of the Final 2019 Annual Renewable Fuel Standards'', Memorandum from Michael Shelby, Dallas Burkholder, and Aaron Sobel available in docket EPA–HQ–OAR–2018–0167.

[137] For the purposes of the cost estimates in this section, EPA has not attempted to adjust the price of the petroleum fuels to account for the impact of the RFS program, since the changes in the renewable fuel volume are relatively modest. Rather, we have simply used the wholesale price projections for gasoline and diesel as reported in EIA's October 2018 STEO.

[138] For this table and all subsequent tables in this section, approximate costs in per gallon cost difference estimates are rounded to the cents place.

[139] For this table and all subsequent tables in this section, approximate resulting costs (other than in per-gallon cost difference estimates) are rounded to two significant figures.

million gallons of CNG/LNG derived from landfill biogas. Based upon the methodology outlined in Section V.A, we use corn kernel fiber as the representative liquid cellulosic biofuel to develop cost estimates of cellulosic ethanol. We estimate a cost difference between cellulosic corn fiber-derived ethanol and gasoline of $0.27–$2.80 on an ethanol-equivalent gallon basis. Next, the per-gallon costs of cellulosic renewable fuel are multiplied by the 5 million gallon increase between the final 2019 cellulosic volume and the final 2018 cellulosic RFS volume requirements to estimate the total costs from the increase in cellulosic ethanol.

For CNG/LNG-derived cellulosic biogas, we provide estimates of the cost of displacing natural gas with CNG/LNG derived from landfill biogas to produce 125 million ethanol-equivalent gallons of cellulosic fuel. To estimate the cost of production of CNG/LNG derived from landfill gas (LFG), EPA uses Version 3.2 of the Landfill Gas Energy Cost Model, or LFG cost-Web. EPA ran the financial cost calculator for projects with a design flow rate of 1,000 and 10,000 cubic feet per minute with the suggested default data. The costs estimated for this analysis exclude any pipeline costs to transport the pipeline quality gas, as well as any costs associated with compressing the gas to CNG/LNG. These costs are not expected to differ significantly between LFG or natural gas. In addition, the cost estimates excluded the gas collection and control system infrastructure at the landfill, as EPA expects that landfills that begin producing high BTU gas in 2019 are very likely to already have this infrastructure in place.[140]

To estimate the illustrative cost impacts of the change in CNG/LNG derived from LFG, we compared the cost of production of CNG/LNG derived from LFG in each case to the projected price for natural gas in 2019 in EIA's October 2018 STEO.[141] Finally, we converted these costs to an ethanol-equivalent gallon basis. The resulting cost estimates are shown in Table V.B.2–1. Adding the cost of cellulosic ethanol to the costs of CNG/LNG landfill gas, the total costs of the final 2019 cellulosic volume compared to 2018 RFS cellulosic volume range from $(2.9)–$23 million.

2. Advanced Biofuel

EPA provides a range of illustrative cost estimates for the increases in the advanced standard of 500 million ethanol-equivalent gallons using two different advanced biofuels. In the first scenario, we assume that all the increase in advanced biofuel volumes is comprised of soybean oil BBD. In the second scenario, we assume that all the increase in the advanced volume is comprised of sugarcane ethanol from Brazil.

Consistent with the analysis in previous annual RFS volume rules, a ''bottom-up'' engineering cost analysis is used that quantifies the costs of producing a gallon of soybean-based biodiesel and then compares that cost to the energy-equivalent gallon of petroleum-based diesel. We compare the cost of biodiesel and diesel fuel at the wholesale stage, since that is when the two are blended together and represents the approximate costs to society absent transfer payments and any additional infrastructure costs. On this basis, EPA estimates the costs of producing and transporting a gallon of biodiesel to the blender in the U.S.

To estimate the illustrative costs of sugarcane ethanol, we compare the cost of sugarcane ethanol and gasoline at the wholesale stage, since that is when the two are blended together and represents the approximate costs to society absent transfer payments and any additional infrastructure costs (*e.g.,* blender pumps). On this basis, EPA estimates the costs of producing and transporting a gallon of sugarcane ethanol to the blender in the U.S. More background information on the cost assessment described in this Section, including details of the data sources used and assumptions made for each of the scenarios, can be found in a Memorandum available in the docket.[142]

Table V.B.2–1 below also presents estimates of per energy-equivalent gallon costs for producing: (1) Soybean biodiesel (in ethanol-equivalent gallons) and (2) Brazilian sugarcane ethanol, relative to the petroleum fuels they replace at the wholesale level. For each of the fuels, these per-gallon costs are then multiplied by the increase in the 2019 non-cellulosic advanced volume relative to the 2018 final advanced standard volume to obtain an overall cost increase of $190–$610 million.

In addition, in Table V.B.2–1, we also present estimates of the total cost of this final rule relative to 2018 RFS fuel volumes. We add the increase in cost of the final 2019 cellulosic standard volume, $(2.9)–$23 million, with the additional costs of the increase in non-cellulosic advanced biofuel volumes resulting from the final 2019 advanced standard volume, $190–$610 million. The overall total costs of this final rule range from $190–$630 million (after rounding to two significant figures).

TABLE V.B.2–1—ILLUSTRATIVE COSTS OF THE 2019 VOLUMES COMPARED TO THE 2018 RFS VOLUMES BASELINE

	Cellulosic Volume
Corn Kernel Fiber Cellulosic Ethanol Costs:	
Cost Difference Between Cellulosic Corn Kernel Fiber Ethanol and Gasoline Per Gallon ($/Ethanol-Equivalent Gallons)	$0.27–$2.80
Change in Volume (Million Ethanol-Equivalent Gallons)	5
Annual Increase in Overall Costs (Million $)	$1.4–$14
CNG/LNG Derived from Biogas Costs:	
Cost Difference Between CNG/LNG Derived from Landfill Biogas and Natural Gas Per Gallon ($/Ethanol-Equivalent Gallons)	$(0.03)–$0.07
Change in Volume (Million Ethanol-Equivalent Gallons)	125
Annual Increase in Overall Costs (Million $)	$(4.3)–$9.0
Range of Annual Increase in Costs with Cellulosic Volume (Million $)	$(2.9)–$23

[140] Details of the data and assumptions used can be found in a Memorandum available in the docket entitled ''Cost Impacts of the Final 2019 Annual Renewable Fuel Standards'', Memorandum from Michael Shelby, Dallas Burkholder, and Aaron Sobel available in docket EPA–HQ–OAR–2018–0167.

[141] Henry Hub Spot price estimate for 2019. EIA, Short Term Energy Outlook (STEO) available in docket EPA–HQ–OAR–2018–0167.

[142] Details of the data and assumptions used can be found in a Memorandum available in the docket entitled ''Cost Impacts of the Final 2019 Annual Renewable Fuel Standards'', Memorandum from Michael Shelby, Dallas Burkholder, and Aaron Sobel available in docket EPA–HQ–OAR–2018–0167.

TABLE V.B.2–1—ILLUSTRATIVE COSTS OF THE 2019 VOLUMES COMPARED TO THE 2018 RFS VOLUMES BASELINE—Continued

	Advanced Volume
Soybean Biodiesel Scenario:	
Cost Difference Between Soybean Biodiesel and Petroleum Diesel Per Gallon ($/Ethanol-Equivalent Gallons)	$0.74–$1.23
Change in Volume (Million Ethanol-Equivalent Gallons)	500
Annual Increase in Overall Costs (Million $)	$370–$610
Brazilian Sugarcane Ethanol Scenario:	
Cost Difference Between Sugarcane Ethanol and Gasoline Per Gallon ($/Ethanol-Equivalent Gallons)	$0.39–$1.04
Change in Volume (Million Ethanol-Equivalent Gallons)	500
Annual Increase in Overall Costs (Million $)	$190–$520
Range of Annual Increase in Overall Costs with Non-Cellulosic Advanced Volume (Million $)	$190–$610
Cellulosic and Advanced Volumes	
Range of Annual Increase in Overall Costs with Cellulosic and Advanced Volume (Million $)[143]	$190–$630

The annual volume-setting process encourages consideration of the RFS program on a piecemeal (*i.e.,* year-to-year) basis, which may not reflect the full, long-term costs and benefits of the program. For the purposes of this final rule, other than the estimates of costs of producing a ''representative'' renewable fuel compared to cost of petroleum fuel, EPA did not quantitatively assess other direct and indirect costs or benefits of changes in renewable fuel volumes. These direct and indirect costs and benefits may include infrastructure costs, investment, climate change impacts, air quality impacts, and energy security benefits, which all are to some degree affected by the annual volumes. For example, we do not have a quantified estimate of the lifecycle GHG or energy security benefits for a single year (*e.g.,* 2019). Also, there are impacts that are difficult to quantify, such as rural economic development and employment changes from more diversified fuel sources, that are not quantified in this rulemaking. While some of these impacts were analyzed in the 2010 final rulemaking that established the current RFS program,[144] we have not analyzed these impacts for the 2019 volume requirements.

VI. Biomass-Based Diesel Volume for 2020

In this section we discuss the BBD applicable volume for 2020. We are setting this volume in advance of those for other renewable fuel categories in light of the statutory requirement in CAA section 211(o)(2)(B)(ii) to establish the applicable volume of BBD for years after 2012 no later than 14 months before the applicable volume will apply. We are not at this time setting the BBD percentage standards that would apply to obligated parties in 2020 but intend to do so in late 2019, after receiving EIA's estimate of gasoline and diesel consumption for 2020. At that time, we will also set the percentage standards for the other renewable fuel types for 2020. Although the BBD applicable volume sets a floor for required BBD use, because the BBD volume requirement is nested within both the advanced biofuel and the total renewable fuel volume requirements, any BBD produced beyond the mandated 2020 BBD volume can be used to satisfy both of these other applicable volume requirements.

A. Statutory Requirements

The statute establishes applicable volume targets for years through 2022 for cellulosic biofuel, advanced biofuel, and total renewable fuel. For BBD, applicable volume targets are specified in the statute only through 2012. For years after those for which volumes are specified in the statute, EPA is required under CAA section 211(o)(2)(B)(ii) to determine the applicable volume of BBD, in coordination with the Secretary of Energy and the Secretary of Agriculture, based on a review of the implementation of the program during calendar years for which the statute specifies the volumes and an analysis of the following factors:

1. The impact of the production and use of renewable fuels on the environment, including on air quality, climate change, conversion of wetlands, ecosystems, wildlife habitat, water quality, and water supply;

2. The impact of renewable fuels on the energy security of the United States;

3. The expected annual rate of future commercial production of renewable fuels, including advanced biofuels in each category (cellulosic biofuel and BBD);

4. The impact of renewable fuels on the infrastructure of the United States, including deliverability of materials, goods, and products other than renewable fuel, and the sufficiency of infrastructure to deliver and use renewable fuel;

5. The impact of the use of renewable fuels on the cost to consumers of transportation fuel and on the cost to transport goods; and

6. The impact of the use of renewable fuels on other factors, including job creation, the price and supply of agricultural commodities, rural economic development, and food prices.

The statute also specifies that the volume requirement for BBD cannot be less than the applicable volume specified in the statute for calendar year 2012, which is 1.0 billion gallons.[145] The statute does not, however, establish any other numeric criteria, or provide any guidance on how the EPA should weigh the importance of the often competing factors and the overarching goals of the statute when the EPA sets the applicable volumes of BBD in years after those for which the statute specifies such volumes. In the period 2013–2022, the statute specifies increasing applicable volumes of cellulosic biofuel, advanced biofuel, and total renewable fuel, but provides no guidance, beyond the 1.0 billion gallon minimum, on the level at which BBD volumes should be set.

In establishing the BBD and cellulosic standards as nested within the advanced biofuel standard, Congress clearly intended to support development of BBD and especially cellulosic biofuels, while also providing an incentive for the growth of other non-specified types of advanced biofuels. In general, the advanced biofuel standard provides an

[143] Summed costs are presented using two significant figures.

[144] RFS2 Regulatory Impact Analysis (RIA). U.S. EPA 2010, Renewable Fuel Standard Program (RFS2) Regulatory Impact Analysis. EPA–420–R–10–006. February 2010. Docket EPA–HQ–OAR–2009–0472–11332.

[145] See CAA section 211(o)(2)(B)(v).

opportunity for other advanced biofuels (advanced biofuels that do not qualify as cellulosic biofuel or BBD) to compete with cellulosic biofuel and BBD to satisfy the advanced biofuel standard after the cellulosic biofuel and BBD standards have been met.

B. Review of Implementation of the Program and the 2020 Applicable Volume of Biomass-Based Diesel

One of the primary considerations in determining the BBD volume for 2020 is a review of the implementation of the program to date, as it affects BBD. This review is required by the CAA, and also provides insight into the capabilities of the industry to produce, import, export, and distribute BBD. It also helps us to understand what factors, beyond the BBD standard, may incentivize the production and import of BBD. Table VI.B.1–1 below shows, for 2011–2017, the number of BBD RINs generated, the number of RINs retired due to export, the number of RINs retired for reasons other than compliance with the annual BBD standards, and the consequent number of available BBD RINs; and for 2011–2019, the BBD and advanced biofuel standards.

TABLE VI.B.1–1—BIOMASS-BASED DIESEL (D4) RIN GENERATION AND ADVANCED BIOFUEL AND BIOMASS-BASED DIESEL STANDARDS IN 2011–2019

[Million RINs or gallons] [146]

	BBD RINs generated	Exported BBD (RINs)	BBD RINs retired, non-compliance reasons	Available BBD RINs [a]	BBD standard (gallons)	BBD standard (RINs)	Advanced biofuel standard (RINs)
2011	1,692	110	98	1,483	800	1,200	1,350
2012	1,737	183	90	1,465	1,000	1,500	2,000
2013	2,739	298	101	2,341	1,280	1,920	2,750
2014	2,710	126	92	2,492	1,630	[b] 2,490	2,670
2015	2,796	133	32	2,631	1,730	[b] 2,655	2,880
2016	4,008	203	52	3,753	1,900	2,850	3,610
2017	3,849	244	35	3,570	2,000	3,000	4,280
2018 [c]	3,898	154	40	3,740	2,100	3,150	4,290
2019	N/A	N/A	N/A	N/A	2,100	3,150	4,920

[a] Available BBD RINs may not be exactly equal to BBD RINs Generated minus Exported RINs and BBD RINs Retired, Non-Compliance Reasons, due to rounding.

[b] Each gallon of biodiesel qualifies for 1.5 RINs due to its higher energy content per gallon than ethanol. Renewable diesel qualifies for between 1.5 and 1.7 RINs per gallon, but generally has an equivalence value of 1.7. While some fuels that qualify as BBD generate more than 1.5 RINs per gallon, EPA multiplies the required volume of BBD by 1.5 in calculating the percent standard per 80.1405(c). In 2014 and 2015 however, the number of RINs in the BBD Standard column is not exactly equal to 1.5 times the BBD volume standard as these standards were established based on actual RIN generation data for 2014 and a combination of actual data and a projection of RIN generation for the last three months of the year for 2015, rather than by multiplying the required volume of BBD by 1.5. Some of the volume used to meet the BBD standard in these years was renewable diesel, with an equivalence value higher than 1.5.

[c] "2018 BBD RINs generated," "Exported BBD," and "BBD RINs retired, Non-Compliance Reasons" are projected based on data through September 2018.

In reviewing historical BBD RIN generation and use, we see that the number of RINs available for compliance purposes exceeded the volume required to meet the BBD standard in 2011, 2012, 2013, 2016 and 2017. Additional production and use of biodiesel was likely driven by a number of factors, including demand to satisfy the advanced biofuel and total renewable fuels standards, the biodiesel tax credit,[147] and favorable blending economics. The number of RINs available in 2014 and 2015 was approximately equal to the number required for compliance in those years, as the standards for these years were finalized at the end of November 2015 and EPA's intent at that time was to set the standards for 2014 and 2015 to reflect actual BBD use.[148] In 2016, with RFS standards established prior to the beginning of the year and the blenders tax credit in place, available BBD RINs exceeded the volume required by the BBD standard by 859 million RINs (30 percent). In 2017, the RFS standards were established prior to the beginning of the year, and the blenders tax credit was only applied retroactively; even without the certainty of a tax credit, the available BBD RINs exceeded the volume required by the BBD standard by 570 million RINs (19 percent). Extrapolated data for 2018 also indicates that available BBD RINs will exceed the BBD standard. This indicates that in certain circumstances there is demand for BBD beyond the required volume of BBD. We also note that while EPA has consistently established the required volume in such a way as to allow non-BBD fuels to compete for market share in the advanced biofuel category, since 2016 the vast majority of non-cellulosic advanced biofuel used to satisfy the advanced biofuel obligations has been BBD.

The prices paid for advanced biofuel and BBD RINs beginning in early 2013 through September 2018 (the last month for which data are available) also support the conclusion that advanced biofuel and/or total renewable fuel standards provide a sufficient incentive for additional biodiesel volume beyond what is required by the BBD standard. Because the BBD standard is nested within the advanced biofuel and total renewable fuel standards, and therefore can help to satisfy three RVOs, we would expect the price of BBD RINs to exceed that of advanced and conventional renewable RINs.[149] If,

[146] Available BBD RINs Generated, Exported BBD RINs, and BBD RINs Retired for Non-Compliance Reasons information from EMTS.

[147] The biodiesel tax credit was reauthorized in January 2013. It applied retroactively for 2012 and for the remainder of 2013. It was once again extended in December 2014 and applied retroactively to all of 2014 as well as to the remaining weeks of 2014. In December 2015 the biodiesel tax credit was authorized and applied retroactively for all of 2015 as well as through the end of 2016. In February 2018 the biodiesel tax credit was authorized and applied retroactively for all of 2017.

[148] See 80 FR 77490–92, 77495 (December 14, 2015).

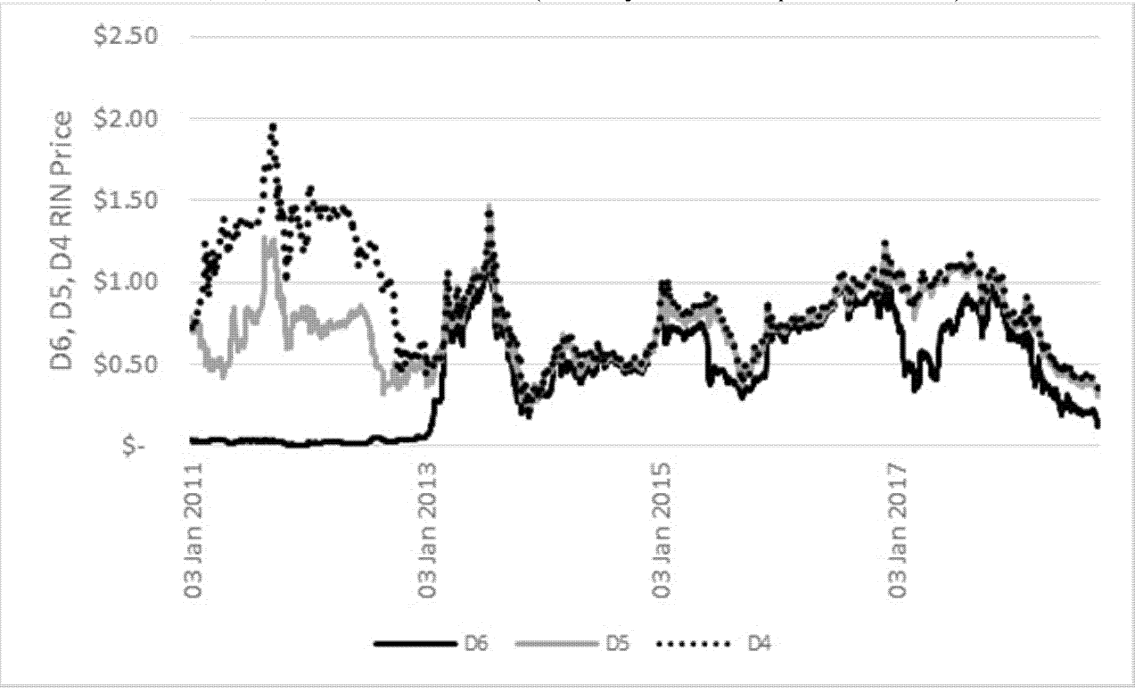
[149] This is because when an obligated party retires a BBD RIN (D4) to help satisfy their BBD obligation,

Continued

however, BBD RINs are being used (or are expected to be used) by obligated parties to satisfy their advanced biofuel obligations, above and beyond the BBD standard, we would expect the prices of advanced biofuel and BBD RINs to converge.[150] Further, if BBD RINs are being used (or are expected to be used) to satisfy obligated parties' total renewable fuel obligation, above and beyond their BBD and advanced biofuel requirements, we would expect the price for all three RIN types to converge.

When examining RIN price data from 2012 through September 2018, shown in Figure VI.B.2–1 below, we see that beginning in early 2013 and through September 2018 the advanced RIN price and BBD RIN prices were approximately equal. Similarly, from early 2013 through late 2016 the conventional renewable fuel and BBD RIN prices were approximately equal. This suggests that the advanced biofuel standard and/or total renewable fuel standard are capable of incentivizing increased BBD volumes beyond the BBD standard. The advanced biofuel standard has incentivized additional volumes of BBD since 2013, while the total standard had incentivized additional volumes of BBD from 2013 through 2016.[151] While final standards were not in place throughout 2014 and most of 2015, EPA had issued proposed rules for both of these years.[152] In each year, the market response was to supply volumes of BBD that exceeded the proposed BBD standard in order to help satisfy the proposed advanced and total biofuel standards.[153] Additionally, the RIN prices in these years strongly suggests that obligated parties and other market participants anticipated the need for BBD RINs to meet their advanced and total biofuel obligations, and responded by purchasing advanced biofuel and BBD RINs at approximately equal prices. We do note, however, that in 2012 the BBD RIN price was significantly higher than both the advanced biofuel and conventional renewable fuel RIN prices. In 2012 the E10 blendwall had not yet been reached, and it was likely more cost effective for most obligated parties to satisfy the portion of the advanced biofuel requirement that exceeded the BBD and cellulosic biofuel requirements with advanced ethanol.

Figure VI.B.2-1
D4, D5, and D6 RIN Prices (January 2011 – September 2018)



RIN Price Source: Argus Media Group

In raising the 2013 BBD volume above the 1 billion gallon minimum mandated by Congress, the EPA sought to ''create greater certainty for both producers of BBD and obligated parties'' while also acknowledging that, ''the potential for somewhat increased costs is appropriate in light of the additional certainty of GHG reductions and enhanced energy security provided by the advanced biofuel volume requirement of 2.75 billion gallons.'' [154] Unknown at that

the nested nature of the BBD standard means that this RIN also counts towards satisfying their advanced and total renewable fuel obligations. Advanced RINs (D5) count towards both the advanced and total renewable fuel obligations, while conventional RINs (D6) count towards only the total renewable fuel obligation.

[150] We would still expect D4 RINs to be valued at a slight premium to D5 and D6 RINs in this case (and D5 RINs at a slight premium to D6 RINs) to reflect the greater flexibility of the D4 RINs to be used towards the BBD, advanced biofuel, and total renewable fuel standard. This pricing has been observed over the past several years.

[151] Although we did not issue a rule establishing the final 2013 standards until August of 2013, we believe that the market anticipated the final standards, based on EPA's July 2011 proposal and the volume targets for advanced and total renewable fuel established in the statute. (76 FR 38844, 38843 July 1, 2011).

[152] See 80 FR 33100 (2014–16 standards proposed June 10, 2015); 78 FR 71732 (2014 standards proposed Nov. 29, 2013).

[153] EPA proposed a BBD standard of 1.28 billion gallons (1.92 billion RINs) for 2014 in our November 2013 proposed rule. The number of BBD RINs available in 2014 was 2.67 billion. EPA proposed a BBD standard of 1.70 billion gallons (2.55 billion RINs) for 2015 in our June 2015 proposed rule. The number of BBD RINs available in 2015 was 2.92 billion.

[154] 77 FR 59458, 59462 (September 27, 2012).

time was the degree to which the required volumes of advanced biofuel and total renewable fuel could incentivize volumes of BBD that exceeded the BBD standard. In 2012 the available supply of BBD RINs exceeded the required volume of BBD by a very small margin (1,545 million BBD RINs were made available for compliance towards meeting the BBD requirement of 1,500 million BBD RINs). The remainder of the 2.0 billion-gallon advanced biofuel requirement was satisfied with advanced ethanol, which was largely imported from Brazil.[155] From 2012 to 2013 the statutory advanced biofuel requirement increased by 750 million gallons. If EPA had not increased the required volume of BBD for 2013, and the advanced biofuel standard had proved insufficient to increase the supply of BBD beyond the statutory minimum of 1.0 billion gallons, an additional 750 million gallons of non-BBD advanced biofuels beyond the BBD standard would have been needed to meet the advanced biofuel volume requirement.

The only advanced biofuel other than BBD available in appreciable quantities in 2012 and 2013 was advanced ethanol, the vast majority of which was imported sugarcane ethanol. EPA had significant concerns as to whether or not the supply of advanced ethanol could increase this significantly (750 million gallons) in a single year. These concerns were heightened by the approaching E10 blendwall, which had the potential to increase the challenges associated with supplying increasing volumes of ethanol to the U.S. If neither BBD volumes nor advanced ethanol volumes increased sufficiently, EPA was concerned that some obligated parties might be unable to acquire the advanced biofuel RINs necessary to demonstrate compliance with their RVOs in 2013. Therefore, as discussed above, EPA increased the volume requirement for BBD in 2013 to help create greater certainty for BBD producers (by ensuring demand for their product above the 1.0 billion gallon statutory minimum) and obligated parties (by ensuring that sufficient RINs would be available to satisfy their advanced biofuel RVOs). Since 2013, however, EPA has gained significant experience implementing the RFS program. As discussed above, RIN generation data has consistently demonstrated that the advanced biofuel volume requirement, and to a lesser degree the total renewable fuel volume requirement, are capable of incentivizing the supply of BBD above and beyond the BBD volume requirement. The RIN generation data also show that while EPA has consistently preserved the opportunity for fuels other that BBD to contribute towards satisfying the required volume of advanced biofuel, these other advanced biofuels have not been supplied in significant quantities since 2013.

TABLE VI.B.1–2—OPPORTUNITY FOR AND RIN GENERATION OF ''OTHER'' ADVANCED BIOFUELS

[Million RINs]

	Opportunity for ''other'' advanced biofuels[a]	Available advanced (D5) RINs	Available BBD (D4) RINs in excess of the BBD requirement[b]
2011	150	225	283
2012	500	597	-35
2013	829	552	421
2014[c]	192	143	2
2015[c]	162	147	−24
2016	530	97	903
2017	969	144	570
2018[d]	852	121	590

[a] The required volume of ''other'' advanced biofuel is calculated by subtracting the number of cellulosic biofuel and BBD RINs required each year from the number of advanced biofuel RINs required. This portion of the advanced standard can be satisfied by advanced (D5) RINs, BBD RINs in excess of those required by the BBD standard, or cellulosic RINs in excess of those required by the cellulosic standard.

[b] The available BBD (D4) RINs in excess of the BBD requirement is calculated by subtracting the required BBD volume (multiplied by 1.5 to account for the equivalence value of biodiesel) required each year from the number of BBD RINs available for compliance in that year. This number does not include carryover RINs, nor do we account for factors that may impact the number of BBD RINs that must be retired for compliance, such as differences between the projected and actual volume of obligated gasoline and diesel.

[c] The 2014 and 2015 volume requirements were established in November 2015 and were set equal to the number of RINs projected to be available for each year.

[d] Available Advanced RINs and available D4 RINs in excess of the BBD requirement are projected based on data through September 2018.

In 2014 and 2015, EPA set the BBD and advanced standards at actual RIN generation, and thus the space between the advanced biofuel standard and the biodiesel standard was unlikely to provide an incentive for ''other'' advanced biofuels. EPA now has data on the amount of ''other'' advanced biofuels produced in 2016 and 2017 as shown in the table above. For 2016 and 2017, the gap between the BBD standard and the advanced biofuel provided an opportunity for ''other'' advanced biofuels to be generated to satisfy the advanced biofuel standard. While the RFS volumes created the opportunity for up to 530 million and 969 million gallons of ''other'' advanced for 2016 and 2017 respectively to be used to satisfy the advanced biofuel obligation, only 97 million and 144 million gallons of ''other'' advanced biofuels were generated. This is significantly less than the volumes of ''other'' advanced available in 2012–2013. Despite creating space within the advanced biofuel standard for ''other'' advanced, in recent years, only a small fraction of that space has been filled with ''other'' advanced, and BBD continues to fill most of the gap between the BBD standard and the advanced standard.

Thus, while the advanced biofuel standard is sufficient to drive biodiesel volume separate and apart from the BBD standard, there would not appear to be a compelling reason to increase the ''space'' maintained for ''other'' advanced biofuel volumes. The overall

[155] 594 million advanced ethanol RINs were generated in 2012.

volume of non-cellulosic advanced biofuel in this final rule increases by 500 million gallons for 2019. Increasing the BBD volume by the same amount would preserve the space already available for other advanced biofuels to compete.

At the same time, the rationale for preserving the ''space'' for ''other'' advanced biofuels remains. We note that the BBD industry in the U.S. and abroad has matured since EPA first increased the required volume of BBD beyond the statutory minimum in 2013. To assess the maturity of the biodiesel industry, EPA compared information on BBD RIN generation by company in 2012 and 2017 (the most recent year for which complete RIN generation by company is available). In 2012, the annual average RIN generation per company producing BBD was about 11 million RINs (about 7.3 million gallons) with approximately 50 percent of companies producing less than 1 million gallons of BBD a year.[156] The agency heard from multiple commenters during the 2012 and 2013 rulemakings that higher volume requirements for BBD would provide greater certainty for the emerging BBD industry and encourage further investment. Since that time, the BBD industry has matured in a number of critical areas, including growth in the size of companies, the consolidation of the industry, and more stable funding and access to capital. In 2012, the BBD industry was characterized by smaller companies with dispersed market share. By 2017, the average BBD RIN generation per company had climbed to almost 33 million RINs (22 million gallons) annually, a 3-fold increase. Only 33 percent of the companies produced less than 1 million gallons of BBD in 2017.[157]

We are conscious of public comments claiming that BBD volume requirements that are a significant portion of the advanced volume requirements effectively disincentivize the future development of other promising advanced biofuel pathways.[158] A variety of different types of advanced biofuels, rather than a single type such as BBD, would increase energy security (*e.g.,* by increasing the diversity of feedstock sources used to make biofuels, thereby reducing the impacts associated with a shortfall in a particular type of feedstock) and increase the likelihood of the development of lower cost advanced biofuels that meet the same GHG reduction threshold as BBD.[159]

We received comments from stakeholders suggesting that the BBD volume standard is unique, as it is required to be set 14 months prior to beginning of the compliance year, in contrast to the advanced standard which is often modified only a month prior to the compliance year. These commenters suggested that EPA should therefore increase the BBD standard to allow for industry to utilize the 14-month notice to make investments. EPA acknowledges this unique aspect of the BBD volume, but still believes a volume of 2.43 billion appropriately provides a floor for guaranteed BBD volume, while also providing space for other advanced biofuels to compete in the market. Based on our review of the data, and the nested nature of the BBD standard within the advanced standard, we conclude that the advanced standard continues to drive the ultimate volume of BBD supplied. However, given that BBD has been the predominant source of advanced biofuel in recent years and the 500 million gallon increase in non-cellulosic advanced biofuel we are finalizing in this rule, we are setting a volume of 2.43 billion gallons of BBD for 2020.

We recognize that the space for other advanced biofuels in 2020 will ultimately depend on the 2020 advanced biofuel volume. While EPA is not establishing the advanced biofuel volume for 2020 in this action, we anticipate that the non-cellulosic advanced biofuel volume for 2020, when established, will be greater than 3.65 billion gallons (equivalent to 2.43 billion gallons of BBD, after applying the 1.5 equivalence ratio). This expectation is consistent with our actions in previous years. Accordingly, we expect that the 2020 advanced biofuel volume, together with the 2020 BBD volume established today, will continue to preserve a considerable portion of the advanced biofuel volume that could be satisfied by either additional gallons of BBD or by other unspecified and potentially less costly types of qualifying advanced biofuels.

C. Consideration of Statutory Factors Set Forth in CAA Section 211(o)(2)(B)(ii)(I)–(VI) for 2020 and Determination of the 2020 Biomass-Based Diesel Volume

The BBD volume requirement is nested within the advanced biofuel requirement, and the advanced biofuel requirement is, in turn, nested within the total renewable fuel volume requirement.[160] This means that any BBD produced beyond the mandated BBD volume can be used to satisfy both these other applicable volume requirements. The result is that in considering the statutory factors we must consider the potential impacts of increasing or decreasing BBD in comparison to other advanced biofuels.[161] For a given advanced biofuel standard, greater or lesser BBD volume requirements do not change the amount of advanced biofuel used to displace petroleum fuels; rather, increasing the BBD requirement may result in the displacement of other types of advanced biofuels that could have been used to meet the advanced biofuels volume requirement. EPA is increasing the BBD volume for 2020 to 2.43 billion gallons from 2.1 billion gallons in 2019 based on our review of the statutory factors and the other considerations noted above and in the 2020 BBD Docket Memorandum. This increase, in conjunction with the statutory increase of 500 million gallons of non-cellulosic advanced biofuel in 2019, would preserve a gap for ''other'' advanced biofuels, that is the difference between the advanced biofuel volume and the sum of the cellulosic biofuel and BBD volumes. This would allow other advanced biofuels to continue to compete with excess volumes of BBD for market share under the advanced biofuel standard, while also supporting further growth in the BBD industry.

Consistent with our approach in setting the final BBD volume requirement for 2019, EPA's primary assessment of the statutory factors for the 2020 BBD applicable volume is that because the BBD requirement is nested within the advanced biofuel volume requirement, we expect that the 2020 advanced volume requirement, when set next year, will determine the level of BBD use, production and imports that occur in 2020.[162] Therefore, EPA

[156] ''BBD RIN Generation by Company 2012, 2016, and 2017 CBI,'' available in EPA docket EPA–HQ–OAR–2018–0167.

[157] Id.

[158] See, *e.g.,* Comments from Advanced Biofuel Association, available in EPA docket EPA–HQ–2018–0167–1277.

[159] All types of advanced biofuel, including BBD, must achieve lifecycle GHG reductions of at least 50 percent. See CAA section 211(o)(1)(B)(i), (D).

[160] See CAA section 211(o)(2)(B)(i)(IV), (II).

[161] While excess BBD production could also displace conventional renewable fuel under the total renewable standard, as long as the BBD applicable volume is lower than the advanced biofuel applicable volume our action in setting the BBD applicable volume is not expected to displace conventional renewable fuel under the total renewable standard, but rather other advanced biofuels. We acknowledge, however, that under certain market conditions excess volumes of BBD may also be used to displace conventional biofuels.

[162] Even though we are not establishing the 2020 advanced biofuel volume requirement as part of this rulemaking, we expect that, as in the past, the 2020 advanced volume requirement will be higher than the 2020 BBD requirement, and, therefore, that the BBD volume requirement for 2020 would not be expected to impact the volume of BBD that is

continues to believe that approximately the same overall volume of BBD would likely be supplied in 2020 even if we were to mandate a somewhat lower or higher BBD volume for 2020 in this final rule. Thus, we do not expect our 2020 BBD volume requirement to result in a significant difference in the factors we consider pursuant to CAA section 211(o)(2)(B)(ii)(I)–(VI) in 2020.

As an additional assessment, we considered in the 2020 BBD docket memorandum [163] the potential impacts on the statutory factors of selecting an applicable volume of BBD other than 2.43 billion gallons in 2020 and also in the longer term. While BBD volumes and resulting impact on the statutory factors found in 211(o)(2)(B)(ii), will not likely be significantly impacted by the 2020 BBD standard in the short term, leaving room for growth of other advanced could have a beneficial impact on certain statutory factors in the long term. Even if BBD volumes were to be impacted by the 2020 BBD standard, setting a requirement higher or lower than 2.43 billion gallons in 2020 would only be expected to affect BBD volumes and the statutory factors found in CAA section 211(o)(2)(B)(ii)(I)–(VI) minimally in 2020. However, we find that over a longer timeframe, providing support for other advanced biofuels could have beneficial effects for a number of the statutory factors.

With the considerations discussed above in mind, as well as our analysis of the factors specified in the statute, we are setting the applicable volume of BBD at 2.43 billion gallons for 2020. This increase, in conjunction with the statutory increase of 500 million gallons of non-cellulosic advanced biofuel in 2019, would continue to preserve a significant gap between the advanced biofuel volume and the sum of the cellulosic biofuel and BBD volumes. This would allow other advanced biofuels to continue to compete with excess volumes of BBD for market share under the advanced biofuel standard. We believe this volume sets the appropriate floor for BBD, and that the volume of advanced biodiesel and renewable diesel actually used in 2020 will be driven by the level of the advanced biofuel and total renewable fuel standards that the Agency will establish for 2020. It also recognizes that while maintaining an opportunity for other advanced biofuels is important, the vast majority of the advanced biofuel used to comply with the advanced biofuel standard in recent years has been BBD. Based on information now available from 2016 and 2017, despite providing a significant degree of space for ''other'' advanced biofuels, smaller volumes of ''other'' advanced have been utilized to meet the advanced standard. EPA believes that the BBD standard we are finalizing today still provides sufficient incentive to producers of ''other'' advanced biofuels, while also acknowledging that the advanced standard has been met predominantly with biomass-based diesel. Our assessment of the required statutory factors, as well as the implementation of the program, supports a volume of 2.43 billion gallons.

VII. Percentage Standards for 2019

The renewable fuel standards are expressed as volume percentages and are used by each obligated party to determine their Renewable Volume Obligations (RVOs). Since there are four separate standards under the RFS program, there are likewise four separate RVOs applicable to each obligated party. Each standard applies to the sum of all non-renewable gasoline and diesel produced or imported.

Sections II through V provide our rationale and basis for the final volume requirements for 2019.[164] The volumes used to determine the percentage standards are shown in Table VII–1.

TABLE VII–1—VOLUMES FOR USE IN DETERMINING THE FINAL 2019 APPLICABLE PERCENTAGE STANDARDS

Cellulosic biofuel	Million ethanol-equivalent gallons	418
Biomass-based diesel	Billion gallons	2.1
Advanced biofuel	Billion ethanol-equivalent gallons	4.92
Renewable fuel	Billion ethanol-equivalent gallons	19.92

For the purposes of converting these volumes into percentage standards, we generally use two decimal places to be consistent with the volume targets as given in the statute, and similarly two decimal places in the percentage standards. However, for cellulosic biofuel we use three decimal places in both the volume requirement and percentage standards to more precisely capture the smaller volume projections and the unique methodology that in some cases results in estimates of only a few million gallons for a single producer.

A. Calculation of Percentage Standards

To calculate the percentage standards, we are following the same methodology for 2019 as we have in all prior years. The formulas used to calculate the percentage standards applicable to producers and importers of gasoline and diesel are provided in 40 CFR 80.1405. The formulas rely on estimates of the volumes of gasoline and diesel fuel, for both highway and nonroad uses, which are projected to be used in the year in which the standards will apply. The projected gasoline and diesel volumes are provided by EIA, and include projections of ethanol and biodiesel used in transportation fuel. Since the percentage standards apply only to the non-renewable gasoline and diesel produced or imported, the volumes of renewable fuel are subtracted out of the EIA projections of gasoline and diesel.

Transportation fuels other than gasoline or diesel, such as natural gas, propane, and electricity from fossil fuels, are not currently subject to the standards, and volumes of such fuels are not used in calculating the annual percentage standards. Since under the regulations the standards apply only to producers and importers of gasoline and diesel, these are the transportation fuels used to set the percentage standards, as well as to determine the annual volume obligations of an individual gasoline or diesel producer or importer under 40 CFR 80.1407.

As specified in the RFS2 final rule,[165] the percentage standards are based on energy-equivalent gallons of renewable fuel, with the cellulosic biofuel, advanced biofuel, and total renewable fuel standards based on ethanol equivalence and the BBD standard based on biodiesel equivalence. However, all RIN generation is based on ethanol-equivalence. For example, the

actually used, produced and imported during the 2020-time period.

[163] ''Memorandum to docket: Statutory Factors Assessment for the 2020 Biomass-Based Diesel (BBD) Applicable Volumes.'' See Docket EPA–HQ–OAR–2018–0167.

[164] The 2019 volume requirement for BBD was established in the 2018 final rule.

[165] See 75 FR 14670 (March 26, 2010).

RFS regulations provide that production or import of a gallon of qualifying biodiesel will lead to the generation of 1.5 RINs. The formula specified in the regulations for calculation of the BBD percentage standard is based on biodiesel-equivalence, and thus assumes that all BBD used to satisfy the BBD standard is biodiesel and requires that the applicable volume requirement be multiplied by 1.5 in order to calculate a percentage standard that is on the same basis (*i.e.,* ethanol-equivalent) as the other three standards. However, BBD often contains some renewable diesel, and a gallon of renewable diesel typically generates 1.7 RINs.[166] In addition, there is often some renewable diesel in the conventional renewable fuel pool. As a result, the actual number of RINs generated by biodiesel and renewable diesel is used in the context of our assessment of the applicable volume requirements and associated percentage standards for advanced biofuel and total renewable fuel, and likewise in obligated parties' determination of compliance with any of the applicable standards. While there is a difference in the treatment of biodiesel and renewable diesel in the context of determining the percentage standard for BBD versus determining the percentage standard for advanced biofuel and total renewable fuel, it is not a significant one given our approach to determining the BBD volume requirement. Our intent in setting the BBD applicable volume is to provide a level of guaranteed volume for BBD, but as described in Section VI.B, we do not expect the BBD standard to be binding in 2019. That is, we expect that actual supply of BBD, as well as supply of conventional biodiesel and renewable diesel, will be driven by the advanced biofuel and total renewable fuel standards.

B. Small Refineries and Small Refiners

In CAA section 211(o)(9), enacted as part of the Energy Policy Act of 2005, and amended by the Energy Independence and Security Act of 2007, Congress provided a temporary exemption to small refineries [167] through December 31, 2010. Congress provided that small refineries could receive a temporary extension of the exemption beyond 2010 based either on the results of a required DOE study, or based on an EPA determination of ''disproportionate economic hardship'' on a case-by-case basis in response to small refinery petitions. In reviewing petitions, EPA, in consultation with the Department of Energy, determines whether the small refinery has demonstrated disproportionate economic hardship, and may grant refineries exemptions upon such demonstration.

EPA has granted exemptions pursuant to this process in the past. However, at this time no exemptions have been approved for 2019, and therefore we have calculated the percentage standards for 2019 without any adjustment for exempted volumes. We are maintaining our approach that any exemptions for 2019 that are granted after the final rule is released will not be reflected in the percentage standards that apply to all gasoline and diesel produced or imported in 2019.

C. Final Standards

The formulas in 40 CFR 80.1405 for the calculation of the percentage standards require the specification of a total of 14 variables covering factors such as the renewable fuel volume requirements, projected gasoline and diesel demand for all states and territories where the RFS program applies, renewable fuels projected by EIA to be included in the gasoline and diesel demand, and exemptions for small refineries. The values of all the variables used for this final rule are shown in Table VII.C–1.[168]

TABLE VII.C–1—VALUES FOR TERMS IN CALCULATION OF THE FINAL 2019 STANDARDS [169]

[Billion gallons]

Term	Description	Value
RFV_{CB}	Required volume of cellulosic biofuel	0.418
RFV_{BBD}	Required volume of biomass-based diesel	2.10
RFV_{AB}	Required volume of advanced biofuel	4.92
RFV_{RF}	Required volume of renewable fuel	19.92
G	Projected volume of gasoline	142.62
D	Projected volume of diesel	56.31
RG	Projected volume of renewables in gasoline	14.53
RD	Projected volume of renewables in diesel	2.75
GS	Projected volume of gasoline for opt-in areas	0
RGS	Projected volume of renewables in gasoline for opt-in areas	0
DS	Projected volume of diesel for opt-in areas	0
RDS	Projected volume of renewables in diesel for opt-in areas	0
GE	Projected volume of gasoline for exempt small refineries	0.00
DE	Projected volume of diesel for exempt small refineries	0.00

Projected volumes of gasoline and diesel, and the renewable fuels contained within them, were provided by EIA in a letter to EPA that is required under the statute, and represent consumption values from the October 2018 version of EIA's Short-Term Energy Outlook.[170]

Using the volumes shown in Table VII.C–1, we have calculated the final percentage standards for 2019 as shown in Table VII.C–2.

TABLE VII.C–2—FINAL PERCENTAGE STANDARDS FOR 2019

Cellulosic biofuel	0.230
Biomass-based diesel	1.73
Advanced biofuel	2.71

[166] Under 40 CFR 80.1415(b)(4), renewable diesel with a lower heating value of at least 123,500 Btu/gallon is assigned an equivalence value of 1.7. A minority of renewable diesel has a lower heating value below 123,500 BTU/gallon and is therefore assigned an equivalence value of 1.5 or 1.6 based on applications submitted under 40 CFR 80.1415(c)(2).

[167] A small refiner that meets the requirements of 40 CFR 80.1442 may also be eligible for an exemption.

[168] To determine the 49-state values for gasoline and diesel, the amount of these fuels used in Alaska is subtracted from the totals provided by EIA because petroleum-based fuels used in Alaska do not incur RFS obligations. The Alaska fractions are determined from the June 29, 2018 EIA State Energy Data System (SEDS), Energy Consumption Estimates.

[169] See ''Calculation of final % standards for 2019'' in docket EPA–HQ–OAR–2018–0167.

[170] ''EIA letter to EPA with 2019 volume projections 10–12–18,'' available in docket EPA–HQ–OAR–2018–0167.

TABLE VII.C–2—FINAL PERCENTAGE STANDARDS FOR 2019—Continued

Renewable fuel	10.97

VIII. Administrative Actions

A. Assessment of the Domestic Aggregate Compliance Approach

The RFS regulations specify an ''aggregate compliance'' approach for demonstrating that planted crops and crop residue from the U.S. complies with the ''renewable biomass'' requirements that address lands from which qualifying feedstocks may be harvested.[171] In the 2010 RFS2 rulemaking, EPA established a baseline number of acres for U.S. agricultural land in 2007 (the year of EISA enactment) and determined that as long as this baseline number of acres was not exceeded, it was unlikely that new land outside of the 2007 baseline would be devoted to crop production based on historical trends and economic considerations. The regulations specify, therefore, that renewable fuel producers using planted crops or crop residue from the U.S. as feedstock in renewable fuel production need not undertake individual recordkeeping and reporting related to documenting that their feedstocks come from qualifying lands, unless EPA determines through one of its annual evaluations that the 2007 baseline acreage of 402 million acres agricultural land has been exceeded.

In the 2010 RFS2 rulemaking, EPA committed to make an annual finding concerning whether the 2007 baseline amount of U.S. agricultural land has been exceeded in a given year. If the baseline is found to have been exceeded, then producers using U.S. planted crops and crop residue as feedstocks for renewable fuel production would be required to comply with individual recordkeeping and reporting requirements to verify that their feedstocks are renewable biomass.

The Aggregate Compliance methodology provided for the exclusion of acreage enrolled in the Grassland Reserve Program (GRP) and the Wetlands Reserve Program (WRP) from the estimated total U.S. agricultural land. However, the 2014 Farm Bill terminated the GRP and WRP as of 2013 and USDA established the Agriculture Conservation Easement Program (ACEP) with wetlands and land easement components. The ACEP is a voluntary program that provides financial and technical assistance to help conserve agricultural lands and wetlands and their related benefits. Under the Agricultural Land Easements (ACEP–ALE) component, USDA helps Indian tribes, state and local governments, and non-governmental organizations protect working agricultural lands and limit non-agricultural uses of the land. Under the Wetlands Reserve Easements (ACEP–WRE) component, USDA helps to restore, protect and enhance enrolled wetlands. The WRP was a voluntary program that offered landowners the opportunity to protect, restore, and enhance wetlands on their property. The GRP was a voluntary conservation program that emphasized support for working grazing operations, enhancement of plant and animal biodiversity, and protection of grassland under threat of conversion to other uses.

USDA and EPA concur that the ACEP–WRE and ACEP–ALE represent a continuation in basic objectives and goals of the original WRP and GRP. Therefore, in preparing this year's assessment of the total U.S. acres of agricultural land, the acreage enrolled in the ACEP–WRE and ACEP–ALE was excluded.

Based on data provided by the USDA Farm Service Agency (FSA) and Natural Resources Conservation Service (NRCS), we have estimated that U.S. agricultural land reached approximately 381 million acres in 2018, and thus did not exceed the 2007 baseline acreage. This acreage estimate is based on the same methodology used to set the 2007 baseline acreage for U.S. agricultural land in the RFS2 final rulemaking, with the GRP and WRP substitution as noted above. Specifically, we started with FSA crop history data for 2018, from which we derived a total estimated acreage of 381,694,332 acres. We then subtracted the ACEP–ALE and ACEP–WRE enrolled areas by the end of Fiscal Year 2018, 798,023 acres, to yield an estimate of 380,896,309 acres or approximately 381 million acres of U.S. agricultural land in 2018. The USDA data used to make this derivation can be found in the docket to this rule.[172] [173]

B. Assessment of the Canadian Aggregate Compliance Approach

The RFS regulations specify a petition process through which EPA may approve the use of an aggregate compliance approach for planted crops and crop residue from foreign countries.[174] On September 29, 2011, EPA approved such a petition from the Government of Canada.

The total agricultural land in Canada in 2018 is estimated at 118.5 million acres; below the 2007 baseline of 123 million acres. This total agricultural land area includes 96.3 million acres of cropland and summer fallow, 12.4 million acres of pastureland and 9.8 million acres of agricultural land under conservation practices. This acreage estimate is based on the same methodology used to set the 2007 baseline acreage for Canadian agricultural land in EPA's response to Canada's petition. The data used to make this calculation can be found in the docket to this rule.

IX. Public Participation

Many interested parties participated in the rulemaking process that culminates with this final rule. This process provided opportunity for submitting written public comments following the proposal that we published on July 3, 2018 (83 FR 31098), and we also held a public hearing on July 18, 2018, at which many parties provided both verbal and written testimony. All comments received, both verbal and written, are available in Docket ID No. EPA–HQ–OAR–2018–0167 and we considered these comments in developing the final rule. Public comments and EPA responses are discussed throughout this preamble and in the accompanying RTC document, which is available in the docket for this action.

X. Statutory and Executive Order Reviews

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

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an analysis of illustrative costs associated with this action. This analysis is presented in Section V of this preamble.

[171] 40 CFR 80.1454(g).

[172] USDA also provided EPA with 2018 data from the discontinued GRP and WRP programs. Given this data, EPA estimated the total U.S. agricultural land both including and omitting the GRP and WRP acreage. In 2018, combined land under GRP and WRP totaled 2,975,165 acres. Subtracting the GRP, WRP, ACEP–WRE, and ACEP–ALE acreage yields an estimate of 377,921,144 acres or approximately 378 million total acres of U.S. agricultural land in 2018. Omitting the GRP and WRP data yields approximately 381 million acres of U.S. agricultural land in 2018.

[173] In providing the 2018 agricultural land data to EPA, USDA provided updated data from 2017. An explanation of this data and a revised estimate of 2017 total U.S. agricultural land can be found in the docket to this rule.

[174] 40 CFR 80.1457.

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

This action is considered an Executive Order 13771 regulatory action. Details on the estimated costs of this final rule can be found in EPA's analysis of the illustrative costs associated with this action. This analysis is presented in Section V of this preamble.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2060–0637 and 2060–0640. The final standards will not impose new or different reporting requirements on regulated parties than already exist for the RFS program.

D. Regulatory Flexibility Act (RFA)

I certify that this 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.

The small entities directly regulated by the RFS program are small refiners, which are defined at 13 CFR 121.201. We have evaluated the impacts of this final rule on small entities from two perspectives: As if the 2019 standards were a standalone action or if they are a part of the overall impacts of the RFS program as a whole.

When evaluating the standards as if they were a standalone action separate and apart from the original rulemaking which established the RFS2 program, then the standards could be viewed as increasing the cellulosic biofuel volume by 130 million gallons and the advanced biofuel and total renewable fuel volume requirements by 630 million gallons between 2018 and 2019. To evaluate the impacts of the volume requirements on small entities relative to 2018, we have conducted a screening analysis [175] to assess whether we should make a finding that this action will not have a significant economic impact on a substantial number of small entities. Currently available information shows that the impact on small entities from implementation of this rule will not be significant. We have reviewed and assessed the available information, which shows that obligated parties, including small entities, are generally able to recover the cost of acquiring the RINs necessary for compliance with the RFS standards through higher sales prices of the petroleum products they sell than would be expected in the absence of the RFS program.[176] This is true whether they acquire RINs by purchasing renewable fuels with attached RINs or purchase separated RINs. The costs of the RFS program are thus generally being passed on to consumers in the highly competitive marketplace. Even if we were to assume that the cost of acquiring RINs were not recovered by obligated parties, and we used the maximum values of the illustrative costs discussed in Section V of this preamble and the gasoline and diesel fuel volume projections and wholesale prices from the October 2018 version of EIA's Short-Term Energy Outlook, and current wholesale fuel prices, a cost-to-sales ratio test shows that the costs to small entities of the RFS standards are far less than 1 percent of the value of their sales.

While the screening analysis described above supports a certification that this rule will not have a significant economic impact on small refiners, we continue to believe that it is more appropriate to consider the standards as a part of ongoing implementation of the overall RFS program. When considered this way, the impacts of the RFS program as a whole on small entities were addressed in the RFS2 final rule, which was the rule that implemented the entire program as required by EISA 2007.[177] As such, the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel process that took place prior to the 2010 rule was also for the entire RFS program and looked at impacts on small refiners through 2022.

For the SBREFA process for the RFS2 final rule, we conducted outreach, fact-finding, and analysis of the potential impacts of the program on small refiners, which are all described in the Final Regulatory Flexibility Analysis, located in the rulemaking docket (EPA–HQ–OAR–2005–0161). This analysis looked at impacts to all refiners, including small refiners, through the year 2022 and found that the program would not have a significant economic impact on a substantial number of small entities, and that this impact was expected to decrease over time, even as the standards increased. For gasoline and/or diesel small refiners subject to the standards, the analysis included a cost-to-sales ratio test, a ratio of the estimated annualized compliance costs to the value of sales per company. From this test, we estimated that all directly regulated small entities would have compliance costs that are less than one percent of their sales over the life of the program (75 FR 14862, March 26, 2010).

We have determined that this final rule will not impose any additional requirements on small entities beyond those already analyzed, since the impacts of this rule are not greater or fundamentally different than those already considered in the analysis for the RFS2 final rule assuming full implementation of the RFS program. This final rule increases the 2019 cellulosic biofuel volume requirement by 130 million gallons and the advanced biofuel and total renewable fuel volume requirements by 630 million gallons relative to the 2018 volume requirements, but those volumes remain significantly below the statutory volume targets analyzed in the RFS2 final rule. Compared to the burden that would be imposed under the volumes that we assessed in the screening analysis for the RFS2 final rule (*i.e.,* the volumes specified in the Clean Air Act), the volume requirements proposed in this rule reduce burden on small entities. Regarding the BBD standard, we are increasing the volume requirement for 2020 by 330 million gallons relative to the 2019 volume requirement we finalized in the 2018 final rule. While this volume is an increase over the statutory minimum value of 1 billion gallons, the BBD standard is a nested standard within the advanced biofuel category, which we are significantly reducing from the statutory volume targets. As discussed in Section VI, we are setting the 2020 BBD volume requirement at a level below what is anticipated will be produced and used to satisfy the reduced advanced biofuel requirement. The net result of the standards being finalized in this action is a reduction in burden as compared to implementation of the statutory volume targets as was assumed in the RFS2 final rule analysis.

While the rule will not have a significant economic impact on a substantial number of small entities, there are compliance flexibilities in the program that can help to reduce impacts

[175] ''Screening Analysis for the Final Renewable Fuel Standards for 2019,'' memorandum from Dallas Burkholder, Nick Parsons, and Tia Sutton to EPA Air Docket EPA–HQ–OAR–2018–0167.

[176] For a further discussion of the ability of obligated parties to recover the cost of RINs see ''Denial of Petitions for Rulemaking to Change the RFS Point of Obligation,'' EPA–420–R–17–008, November 2017.

[177] 75 FR 14670 (March 26, 2010).

on small entities. These flexibilities include being able to comply through RIN trading rather than renewable fuel blending, 20 percent RIN rollover allowance (up to 20 percent of an obligated party's RVO can be met using previous-year RINs), and deficit carry-forward (the ability to carry over a deficit from a given year into the following year, providing that the deficit is satisfied together with the next year's RVO). In the RFS2 final rule, we discussed other potential small entity flexibilities that had been suggested by the SBREFA panel or through comments, but we did not adopt them, in part because we had serious concerns regarding our authority to do so.

Additionally, we realize that there may be cases in which a small entity may be in a difficult financial situation and the level of assistance afforded by the program flexibilities is insufficient. For such circumstances, the program provides hardship relief provisions for small entities (small refiners), as well as for small refineries.[178] As required by the statute, the RFS regulations include a hardship relief provision (at 40 CFR 80.1441(e)(2)) that allows for a small refinery to petition for an extension of its small refinery exemption at any time based on a showing that the refinery is experiencing a ''disproportionate economic hardship.'' EPA regulations provide similar relief to small refiners that are not eligible for small refinery relief (see 40 CFR 80.1442(h)). EPA has currently identified a total of 9 small refiners that own 11 refineries subject to the RFS program, all of which are also small refineries.

We evaluate these petitions on a case-by-case basis and may approve such petitions if it finds that a disproportionate economic hardship exists. In evaluating such petitions, we consult with the U.S. Department of Energy and consider the findings of DOE's 2011 Small Refinery Study and other economic factors. To date, EPA has adjudicated petitions for exemption from 29 small refineries for the 2017 RFS standards (8 of which were owned by a small refiner).[179]

In sum, this final rule will not change the compliance flexibilities currently offered to small entities under the RFS program (including the small refinery hardship provisions we continue to implement) and available information shows that the impact on small entities from implementation of this rule will not be significant viewed either from the perspective of it being a standalone action or a part of the overall RFS program. We have therefore concluded that this action will have no net regulatory burden for directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This 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. This action implements mandates specifically and explicitly set forth in CAA section 211(o) and we believe that this action represents the least costly, most cost-effective approach to achieve the statutory requirements.

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 action does not have tribal implications as specified in Executive Order 13175. This action will be implemented at the Federal level and affects transportation fuel refiners, blenders, marketers, distributors, importers, exporters, and renewable fuel producers and importers. Tribal governments will be affected only to the extent they produce, purchase, or use regulated fuels. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that 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 implements specific standards established by Congress in statutes (CAA section 211(o)) and 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 a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action establishes the required renewable fuel content of the transportation fuel supply for 2019, consistent with the CAA and waiver authorities provided therein. The RFS program and this rule are designed to achieve positive effects on the nation's transportation fuel supply, by increasing energy independence and security and lowering lifecycle GHG emissions of transportation fuel.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

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 regulatory action does not affect the level of protection provided to human health or the environment by applicable air quality standards. This action does not relax the control measures on sources regulated by the RFS regulations and therefore will not cause emissions increases from these sources.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is a ''major rule'' as defined by 5 U.S.C. 804(2).

XI. Statutory Authority

Statutory authority for this action comes from section 211 of the Clean Air Act, 42 U.S.C. 7545. Additional support for the procedural and compliance related aspects of this final rule comes from sections 114, 208, and 301(a) of the Clean Air Act, 42 U.S.C. 7414, 7542, and 7601(a).

[178] See CAA section 211(o)(9)(B).

[179] EPA is currently evaluating 7 additional 2017 petitions (1 of which is owned by a small refiner) and 15 additional 2018 petitions (7 of which are owned by a small refiner), bringing the total number of petitions for 2017 to 36 and for 2018 to 15. More information on Small Refinery Exemptions is available on EPA's public website at: *https://www.epa.gov/fuels-registration-reporting-and-compliance-help/rfs-small-refinery-exemptions.*

List of Subjects in 40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Diesel fuel, Fuel additives, Gasoline, Imports, Oil imports, Petroleum, Renewable fuel.

Dated: November 30, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons set forth in the preamble, EPA is amending 40 CFR part 80 as follows:

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

■ 1. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

Subpart M—Renewable Fuel Standard

■ 2. Section 80.1405 is amended by adding paragraph (a)(10) to read as follows:

§ 80.1405 What are the Renewable Fuel Standards?

(a) * * *

(10) *Renewable Fuel Standards for 2019.*

(i) The value of the cellulosic biofuel standard for 2019 shall be 0.230 percent.

(ii) The value of the biomass-based diesel standard for 2019 shall be 1.73 percent.

(iii) The value of the advanced biofuel standard for 2019 shall be 2.71 percent.

(iv) The value of the renewable fuel standard for 2019 shall be 10.97 percent.

* * * * *

[FR Doc. 2018–26566 Filed 12–10–18; 8:45 am]

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Part III

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910
Revising the Beryllium Standard for General Industry; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2018–0003]

RIN 1218–AD20

Revising the Beryllium Standard for General Industry

AGENCY: Occupational Safety and Health Administration (OSHA); Labor.

ACTION: Proposed rule; request for comment.

SUMMARY: On January 9, 2017, OSHA issued a final rule adopting a comprehensive general industry standard for occupational exposure to beryllium and beryllium compounds. In this proposed rule, OSHA is proposing to modify the general industry standard to clarify certain provisions and simplify or improve compliance. Proposed changes would maintain safety and health protections for workers and are designed to enhance worker protections overall by ensuring that the rule is well-understood and compliance is more straightforward.

DATES: Comments to this proposal, hearing requests, and other information must be submitted (transmitted, postmarked, or delivered) by February 11, 2019. All submissions must bear a postmark or provide other evidence of the submission date.

ADDRESSES: The public can submit comments, hearing requests, and other material, identified by Docket No. OSHA–2018–0003, using any of the following methods:

Electronically: Submit comments and attachments, as well as hearing requests and other information, electronically at *http://www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions online for submitting comments. Note that this docket may include several different **Federal Register** notices involving active rulemakings, so it is extremely important to select the correct notice or RIN number (RIN 1218–AD20) when submitting comments for this rulemaking. After accessing ''all documents and comments'' in the docket (OSHA–2018–0003), check the ''proposed rule'' box in the column headed ''Document Type,'' find the document posted on the date of publication of this document, and click the ''Submit a Comment'' link. Additional instructions for submitting comments are available from the *http://www.regulations.gov* homepage.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693–1648. OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (*e.g.,* studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Docket No. OSHA–2018–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. These attachments must clearly identify the sender's name, the date, the subject, and the docket number (OSHA–2018–0003) so that the Docket Office can attach them to the appropriate document.

Regular mail, express delivery, hand delivery, and messenger (courier) service: Submit comments and any additional material to the OSHA Docket Office, Docket No. OSHA–2018–0003, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–2350. OSHA's TTY number is (877) 889–5627. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express delivery, hand delivery, and messenger service. The Docket Office will accept deliveries (express delivery, hand delivery, messenger service) during the Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency's name, the title of the rulemaking (Beryllium Standard: Notice of Proposed Rulemaking), and the docket number (OSHA–2018–0003). OSHA will place comments and other material, including any personal information, in the public docket without revision, and the comments and other material will be available online at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others), such as Social Security Numbers, birth dates, and medical data.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the above address. The electronic docket for this proposed rule established at *http://www.regulations.gov* contains most of the documents in the docket. However, some information (*e.g.,* copyrighted material) is not available publicly to read or download through this website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT: *Press inquiries:* Mr. Frank Meilinger, OSHA Office of Communications, Occupational Safety and Health Administration; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information and technical inquiries: William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Occupational Safety and Health Administration; telephone (202) 693–1950.

Copies of this Federal Register notice and news releases: Electronic copies of these documents are available at OSHA's web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

On January 9, 2017, OSHA published the final rule Occupational Exposure to Beryllium and Beryllium Compounds in the **Federal Register** (82 FR 2470). OSHA concluded that employees exposed to beryllium and beryllium compounds at the preceding permissible exposure limits (PELs) were at significant risk of material impairment of health, specifically chronic beryllium disease (CBD) and lung cancer. OSHA concluded in the final rule that the new 8-hour time-weighted average (TWA) PEL of 0.2 $\mu g/m^3$ would reduce this significant risk to the maximum extent feasible. In the final rule OSHA issued three separate beryllium standards—general industry, shipyards, and construction. In addition to the revised PEL, for each of the three standards the final rule also established a new short-term exposure limit (STEL) of 2.0 $\mu g/m^3$ over a 15-minute sampling period and

an action level of 0.1 μg/m³ as an 8-hour TWA, along with a number of ancillary provisions intended to provide additional protections to employees. These included requirements for exposure assessment, methods for controlling exposure, respiratory protection, personal protective clothing and equipment, housekeeping, medical surveillance, hazard communication, and recordkeeping similar to those found in other OSHA health standards.

This proposal would amend the beryllium standard for general industry to clarify certain provisions—with proposed changes designed to facilitate application of the standard consistent with the intent of the 2017 final rule—and simplify or improve compliance, preventing costs that may flow from misinterpretation or misapplication of the standard. OSHA's discussion of the estimated costs and cost savings for this proposed rule can be found in the preliminary economic analysis (PEA). The 2017 Beryllium Final Rule went into effect on May 20, 2017, and some compliance obligations began on May 11, 2018. The compliance obligations affected by this rulemaking will begin on December 12, 2018 (83 FR 39351). Other compliance obligations under the standard do not commence until 2019 or 2020.

OSHA believes that the standard as modified by this proposal would provide equivalent protection to the current standard. Accordingly, while this rulemaking is pending, compliance with the standard as modified by this proposal will be accepted as compliance with the standard.

II. Discussion of Proposed Changes

OSHA proposes to modify several of the general industry standard's definitions, along with the provisions for methods of compliance, personal protective clothing and equipment, hygiene areas and practices, housekeeping, medical surveillance, communication of hazards, and recordkeeping. OSHA believes that the proposed changes would maintain safety and health protections for workers. The proposed changes are further designed to enhance worker protections overall by ensuring that the rule is well-understood and compliance is more straightforward.

A. Definitions

Paragraph (b) of the beryllium standard for general industry (82 FR 2470, as modified by 83 FR 19936) addresses changes to the definitions of specific key terms used in the standard. OSHA is proposing to change or add six terms in the definitions paragraph.

OSHA is proposing to add the following definition for *beryllium sensitization:* ''a response in the immune system of a specific individual who has been exposed to beryllium. There are no associated physical or clinical symptoms and no illness or disability with beryllium sensitization alone, but the response that occurs through beryllium sensitization can enable the immune system to recognize and react to beryllium. While not every beryllium-sensitized person will develop CBD, beryllium sensitization is essential for development of CBD.'' The agency is proposing to add this definition in order to provide additional clarification of other provisions in the standard, such as the definitions of *chronic beryllium disease* (CBD) and *confirmed positive* and the provisions for medical surveillance (k) and hazard communication (m). The proposed addition of a definition for *beryllium sensitization* would not change employer obligations under provisions (k) and (m) and would not affect employee protections.

In the 2017 final beryllium rule (82 FR 2470), OSHA found that individuals sensitized through either the dermal or inhalation exposure pathways respond to beryllium through the formation of a beryllium-protein complex, which then binds to T-cells stimulating a beryllium-specific immune response (82 FR 2494). The formation of the T-cell-beryllium-protein complex that results in beryllium sensitization may not manifest in any outward clinical symptoms in the lung (82 FR 2491), and most who are sensitized may not show any symptoms at all. While it may be rare for those sensitized through dermal exposure to exhibit any outward signs or symptoms, dermal sensitization has been associated with skin granulomas and contact dermatitis. Dermal exposure may also result in dermal irritation, which can be indistinguishable from contact dermatitis (82 FR 2527–2528). It should be noted that beryllium, beryllium oxide, and other soluble and poorly soluble forms of beryllium have been classified as a skin irritant (category 2) in accordance with the EU Classification, Labelling and Packaging Regulation (Document ID OSHA–H005C–2006–0870–1669, p. 2).

As OSHA determined in the final beryllium rule, after an individual has been sensitized, subsequent beryllium exposures via inhalation can progress to serious lung disease through the formation of granulomas and fibrosis (82 FR 2491–2498). Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of sensitization (NAS, 2008, Document ID OSHA–H005C–2006–0870–1355). Therefore, the proposed definition explaining that beryllium sensitization is essential for development of CBD is consistent with the agency's findings in the final rule.

Paragraph (b) of the general industry beryllium standard defines *beryllium work area* as any work area containing a process or operation that can release beryllium and that involves material that contains at least 0.1 percent beryllium by weight; and, where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is the potential for dermal contact with beryllium. In addition to paragraphs (e)(1)(i) and (e)(2)(i), which require employers to establish, maintain, and demarcate a beryllium work area wherever this definition is met, the presence of a beryllium work area also triggers several other requirements in the standard: Paragraphs (f)(1)(i)(D) and (f)(1)(i)(F) (written exposure control plan requirements); paragraph (f)(2) (required exposure controls); paragraphs (i)(1) (general hygiene practices) and (i)(2) (change rooms); paragraphs (j)(1)(i) and (j)(2) (housekeeping requirements); and paragraph (m)(4)(ii)(B) (employee training).

OSHA proposes to modify this definition to clarify when an area of a workplace must be considered a beryllium work area. The proposed revision would define *beryllium work area* as any work area where materials that contain at least 0.1 percent beryllium by weight are processed during an operation listed in Appendix A, regardless of exposure level; or where employees are, or can reasonably be expected to be, exposed to airborne beryllium at or above the action level. In conjunction with this change, OSHA proposes to revise Appendix A so that it contains proposed Table A.1: Operations for Establishing Beryllium Work Areas Where Processing Materials Containing at Least 0.1 Percent Beryllium by Weight, which provides a list of operations commonly performed while processing beryllium metal, beryllium composites, beryllium alloys, or beryllium oxides that have the potential for exposure to airborne beryllium through the generation of dust, mist, and/or fumes. The list of operations in Table A.1 was compiled based on the experience of Materion Corporation (Materion), the primary beryllium manufacturer in the United States, and the USW, the primary union representing employees with beryllium exposure, and is divided into three categories: (1) Beryllium Metal Alloy

Operations (generally <10% beryllium by weight); (2) Beryllium Composite Operations (generally >10% beryllium by weight) and Beryllium Metal Operations; and (3) Beryllium Oxide Operations. OSHA requests comment on whether the new definition of *beryllium work area* captures the operations and processes of concern. In particular, OSHA requests comment on whether the operations in Table A.1 are appropriate, whether any operations should be added, and whether any operations listed in one category should also be included in any other category. The listed operations are explained in more detail in a separate document available in the docket (Document ID 0014).

This proposed modification to the definition of *beryllium work area* is intended to improve compliance with the standard by providing greater clarity to employers regarding when and where beryllium work areas should be established in a workplace. Requiring employers to identify, establish, and demarcate beryllium work areas is a novel approach to workplace hazard management in OSHA standards, because beryllium work areas must be established in addition to regulated areas and in some locations where airborne exposures do not exceed the PELs. Based on feedback from stakeholders, OSHA has preliminarily determined that the proposed revision to the definition of *beryllium work area* would ensure that the standard's requirements related to beryllium work areas are workable and properly understood.

Based on a joint model standard that OSHA received from Materion and the United Steelworkers (USW) that included a similar provision (Document ID OSHA–H005C–2006–0870–0754), OSHA's original NPRM for the beryllium standard proposed that *beryllium work area* be defined as any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium (80 FR at 47778). Unlike regulated areas, beryllium work areas were not tied to a specific level of exposure, but rather were triggered by the presence of airborne beryllium at any level. Some stakeholders commented in support of the proposed definition, but others expressed concern that the definition was vague and should be triggered on a measurable threshold level of exposure. Some commenters also expressed concern that the definition was overly broad and could be interpreted as applying to most or all areas of a worksite, regardless of the work processes or operations occurring in those areas (82 FR at 2659–60). NIOSH commented that the proposed definition's focus on airborne beryllium did not account for the potential contribution of dermal exposure to total exposure.

In the final standard, OSHA modified the definition of *beryllium work area* so that it covered any work area containing a process or operation that can release beryllium where employees are, or can reasonably be expected to be, exposed to airborne beryllium at any level or where there is potential for dermal contact with beryllium. OSHA explained in the preamble to the final rule that triggering the requirement of creating a beryllium work area on a specific threshold level of exposure would be insufficiently protective of workers, but explained that the agency did not intend for a beryllium work area to be established in areas where work processes or operations that release beryllium do not occur, such as where employees handle articles containing beryllium (82 FR at 2659–60). Rather, the purpose of establishing beryllium work areas is to identify and demarcate areas within a facility where processes or operations release beryllium so that necessary control measures can be implemented, such as those designed to prevent the migration of beryllium to other areas where beryllium is not processed or released. The definition of *beryllium work area* in the final standard clarified this intent by specifying that a beryllium work area contains processes or operations that release beryllium to which workers could be exposed. Additionally, the modified definition in the final standard accounted for NIOSH's concern by including the potential for dermal contact with beryllium in the definition.

OSHA further modified the definition of *beryllium work area* in the 2018 direct final rule to clarify OSHA's intent that the provisions triggered by the presence of a beryllium work area only apply to areas where there are processes or operations that involve materials that contain at least 0.1 percent beryllium by weight (83 FR 19936, 19938–39 (May 7, 2018)). By specifying that a beryllium work area is a work area that both contains a process or operation that can release beryllium and involves material that contains at least 0.1 percent beryllium by weight, the revised definition was intended to make clear that the provisions associated with beryllium work areas do not apply where processes and operations involve only materials containing trace amounts of beryllium (*i.e.,* less than 0.1 percent beryllium by weight).

Additional feedback from stakeholders has led OSHA to believe that the definition of *beryllium work area* may require further revision in order to make the standard workable and understandable. In particular, stakeholders expressed concern to OSHA that defining a beryllium work area as including areas where employees are, or can reasonably be expected to be, exposed to any level of airborne beryllium, and where the potential for dermal contact with beryllium exists, could lead to the designation of entire facilities as beryllium work areas, because minute quantities of beryllium can be detected in areas of a facility that are distant from areas containing beryllium-releasing processes and operations. As explained in the 2017 final rule preamble, this was not OSHA's intent (82 FR at 2660). Rather, OSHA intended to capture only those areas of a facility where beryllium-generating processes or operations are located. (Id.) Stakeholders requested that OSHA provide a list of operations that are known to release airborne beryllium, which would allow employers to more accurately identify where beryllium work areas must be established and demarcated at their workplaces.

In response to this feedback, OSHA is proposing to further modify the definition of *beryllium work area* to provide clarity for employers on where and when to establish a beryllium work area so as to minimize beryllium exposure and the migration of beryllium into the general work area. First, OSHA is proposing to provide a list of operations that are commonly performed when processing beryllium materials and are known to generate airborne beryllium (see proposed Appendix A), and proposes to revise the definition of *beryllium work area* so that any work area where an operation that is listed in proposed Appendix A occurs and involves materials containing at least 0.1 percent beryllium by weight is a beryllium work area. For work areas where no operations listed in proposed Appendix A occur, the proposed definition would require a beryllium work area wherever materials containing at least 0.1 percent beryllium by weight are processed and where employees are, or can be reasonably expected to be, exposed to airborne beryllium at or above the action level. Although OSHA has preliminarily determined that the operations listed in proposed Appendix A include the general industry operations that are known to release beryllium, OSHA included this second prong of the proposed definition, which is triggered by actual or reasonably expected

airborne exposure at or above the action level, to account for any additional beryllium-releasing operations that may exist or may be developed in the future. OSHA believes these modifications would improve employers' ability to comply with the standard by clarifying the work areas where a beryllium work area exists without reducing protections for employees.

Unlike the current definition, the proposed definition of *beryllium work area* would not expressly state that a beryllium work area exists where there is potential for dermal contact with beryllium. OSHA believes that removing the reference to dermal contact with beryllium would make it less likely that the definition could be erroneously interpreted as extending to an entire facility and would not reduce employee protection from the effects of skin exposure to beryllium. Requiring employers to establish and demarcate entire facilities as beryllium work areas was not OSHA's intent (82 FR at 2660). And OSHA is unaware of work areas containing beryllium-releasing processes or operations that have a potential for dermal contact that are not included in the proposed Appendix A or generate airborne exposures at or above the action level. OSHA intends the proposed definition to be as protective as the current definition, while more clearly avoiding the perception that entire facilities need to be treated as beryllium work areas. OSHA requests comment on these issues, and in particular, whether there are any operations or processes that trigger beryllium work areas under the current rule that would not be covered under the proposed definition. OSHA also seeks comment on alternative approaches to identifying beryllium processes and operations that generate exposures of concern, and how those approaches might avoid inclusion of entire facilities.

The proposed revised criteria for establishing a beryllium work area would continue to protect workers directly exposed in beryllium work areas, while also reducing potential exposure for workers who work outside these areas through the following provisions that apply in beryllium work areas:

- The requirement to establish, implement, and maintain a written exposure control plan, including procedures for minimizing cross-contamination within beryllium work areas and minimizing migration of beryllium from beryllium work areas to other areas (paragraphs (f)(1)(i)(D), (f)(1)(i)(F));
- The requirement to provide at least one method of exposure control (material or process substitution, isolation, local exhaust ventilation, or process control) for each operation in a beryllium work area that releases airborne beryllium (paragraph (f)(2)(ii)), unless exempt under paragraph (f)(2)(iii);
- The requirement to provide and ensure the use of washing facilities for employees working in a beryllium work area (paragraph (i)(1));
- The requirements to maintain surfaces in beryllium work areas as free as practicable of beryllium and ensure surfaces are appropriately cleaned (paragraphs (j)(1)(i) and (j)(2)); and
- The requirement to ensure that employees know where beryllium work areas in the facility are located (paragraph (m)(4)(ii)(B)).

Moreover, the standard's PPE requirements to protect against dermal exposure to beryllium do not depend on the existence of a beryllium work area. The standard requires employers to provide and ensure the use of appropriate PPE whenever there is a reasonable expectation of dermal contact with beryllium, regardless of whether or not the area is a beryllium work area (see paragraph (h)(1)(ii)). OSHA is not proposing to change that requirement.

OSHA is also proposing to add two references to dermal contact with beryllium to paragraph (i), Hygiene areas and practices, to account for the proposed removal of the potential for dermal contact with beryllium from the definition of beryllium work area (see Discussion of Proposed Changes to paragraph (i)). Paragraph (i) currently requires employers to provide washing facilities and a designated change room to each employee working in a beryllium work area (see paragraphs (i)(1)(i) and (i)(2)). Because OSHA still intends for the requirements to provide washing facilities and change rooms to apply to employees who can reasonably be expected to have dermal contact with beryllium, regardless of whether they work in a beryllium work area, OSHA is proposing (1) to revise paragraphs (i)(1) so that its requirement to provide washing facilities also applies to any employee who can reasonably be expected to have dermal contact with beryllium; and (2) to revise paragraph (i)(2) so that employers must provide change rooms to employees who are required to use personal protective clothing or equipment under paragraph (h)(1)(ii), which requires the use of PPE where there is a reasonable expectation of dermal contact with beryllium. As explained above, OSHA expects that, under the proposed revisions to the definitions, employees working in a beryllium work area would reasonably be expected to have dermal contact with beryllium. Thus, should the reference to potential dermal contact with beryllium be removed from the definition of beryllium work area as proposed, OSHA believes that these proposed modifications to paragraph (i), together with the existing requirements for PPE where dermal contact with beryllium is reasonably anticipated, would continue to protect employees from the effects of skin exposure to beryllium (see discussion of proposed revisions to the definition of *dermal contact with beryllium* later in this section for explanation of the impact of the revisions on the hygiene and PPE provisions).

In summary, OSHA believes that these proposed changes would improve employers' ability to comply with the standard by clarifying where beryllium work areas exist, while maintaining the agency's intent to establish beryllium work areas where processes release significant amounts of airborne beryllium and to protect employees from skin exposure to beryllium. OSHA expects that these proposed changes would maintain safety and health protections for workers. OSHA requests comment on these proposed changes, including whether the list of operations in proposed Appendix A adequately covers the operations where airborne exposures are likely and whether operations that trigger the creation of a beryllium work area also give rise to a reasonable expectation of dermal contact with beryllium within the beryllium work area.

OSHA is also proposing to amend the definition of *CBD diagnostic center* to clarify certain requirements used to qualify an existing medical facility as a CBD diagnostic center. The proposed clarification would not change the employer requirement to offer a follow-up examination at a CBD diagnostic center to employees meeting the criteria set forth in paragraph (k)(2)(ii). OSHA is proposing *CBD diagnostic center* to mean a medical diagnostic center that has a pulmonologist or pulmonary specialist on staff and on-site facilities to perform a clinical evaluation for the presence of CBD. The proposed definition also states that a CBD diagnostic center must have the capacity to perform pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. In the proposed definition, the CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for

appropriate diagnostic testing within 24 hours and the pulmonologist or pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

The proposed definition includes the following changes to the current definition of *CBD diagnostic center.* First, the agency is proposing changing the language to reflect the agency's intent that pulmonologists or pulmonary specialists be on staff at a CBD diagnostic center. Whereas the current definition specifies only that a CBD diagnostic center must have a pulmonary specialist, OSHA is proposing to add the term ''pulmonologist'' to clarify that either type of specialist is qualified to perform a clinical evaluation for the presence of CBD. Additionally, the current definition states that a CBD diagnostic center has an on-site specialist. OSHA is proposing to change the language to state that a CBD diagnostic center must have a pulmonologist or pulmonary specialist on staff, rather than on site, to clarify that such specialists need not necessarily be on site at all times.

An additional proposed change to *CBD diagnostic center* would clarify that the diagnostic center must have the capacity to do any of the listed tests that a pulmonary specialist or pulmonologist may deem necessary. As currently written, the definition could be misinterpreted to mean that any clinical evaluation for CBD performed at a CBD diagnostic center must include pulmonary testing, bronchoalveolar lavage, and transbronchial biopsy. The agency's intent is not to dictate what tests a specialist should include, but to ensure that any facility has the capacity to perform any of these tests, which are commonly needed to diagnose CBD. Therefore, the agency is proposing to modify part of the current definition from ''[t]his evaluation must include pulmonary function testing . . .'' to ''[t]he CBD diagnostic center must have the capacity to perform pulmonary function testing . . . '' These changes to the definition of *CBD diagnostic center* are clarifying in nature, and OSHA expects they would maintain safety and health protections for workers.

The agency is also proposing a clarification to the definition of *chronic beryllium disease (CBD).* For the purposes of this standard, the agency is proposing *chronic beryllium disease* to mean a chronic granulomatous lung disease caused by inhalation of airborne beryllium by an individual who is beryllium-sensitized. The proposed definition includes several changes to the current definition of *chronic beryllium disease.*

First, OSHA proposes to alter the current definition by adding the term ''granulomatous'' to better distinguish this disease from other occupationally associated chronic pulmonary diseases of inflammatory origin. A granulomatous lung formation is a focal collection of inflammatory cells (*e.g.,* T-cells) creating a nodule in the lung (Ohshimo et al., 2017, Document ID OSHA–H005C–2006–0870–2171). The formation of the type of lung granuloma specific to a beryllium immune response can only occur in those with CBD (82 FR 2492–2502).

An additional proposed clarification to the definition of *chronic beryllium disease* would change ''associated with airborne exposure to beryllium'' to ''caused by inhalation of airborne beryllium.'' This proposed change would be more consistent with the findings in the beryllium final rule that indicate beryllium is the causative agent for CBD and that CBD only occurs after inhalation of beryllium (82 FR 2513). A further proposed change includes the addition of ''by an individual who is beryllium sensitized.'' This proposed change would clarify OSHA's finding that beryllium sensitization is essential in the development of CBD (82 FR 2492).

OSHA is proposing to modify the definition of *confirmed positive* to mean the person tested has had two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results obtained within the 30 day follow-up test period required after a first abnormal or borderline BeLPT test result. It also means the result of a more reliable and accurate test indicating a person has been identified as having beryllium sensitization. The proposed definition includes several changes to the current definition of *confirmed positive.*

First, the agency is proposing to change the definition of *confirmed positive* by removing the phrase ''beryllium sensitization'' from the first part of the definition, which currently states that the person tested has beryllium sensitization, as indicated by two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results. The proposed change would emphasize OSHA's intent that *confirmed positive* should act as a trigger for continued medical monitoring and surveillance for the purposes of this standard and is not intended as a scientific or general-purpose definition of beryllium sensitization.

The term *confirmed positive* originates from a study that described the findings from a large-scale interlaboratory testing scheme (Stange et al., 2004, Document ID OSHA–H005C–2006–0870–1402). Stange et al. demonstrated that when samples with abnormal findings from one lab were retested in a second lab, the reliability of the results increased. As OSHA discussed in the preamble to the final rule, individuals who are confirmed positive through two abnormal BeLPT test results, an abnormal and a borderline, or three borderlines may be at risk for developing CBD (82 FR 2646). Whether or not individuals are necessarily considered to be beryllium-sensitized at the time of the BeLPT findings is less of a consideration than is the understanding that these individuals may be at risk for developing CBD and should therefore be offered continued medical surveillance, an evaluation at a CBD diagnostic center, and medical removal protection.

An additional proposed change to *confirmed positive* would include clarification that the findings of two abnormal, one abnormal and one borderline, or three borderline results need to occur within the 30-day follow-up test period required after a first abnormal or borderline BeLPT test result. After publication of the final rule, stakeholders suggested to OSHA that the definition of *confirmed positive* could be interpreted as meaning that findings of two abnormal, one abnormal and one borderline, or three borderline results over any time period, even as long as 10 years, would result in the employee being confirmed positive. This was not the agency's intent, as such a timeframe may lead to false positives and thereby not enhance employee protections. Therefore, OSHA is proposing a clarification that any combination of test results specified in the definition must result from the tests conducted in one 30-day cycle of testing, including the initial test and the retesting offered when an initial result is a single abnormal result or borderline, in order to be considered confirmed positive.

As outlined in paragraph (k)(3)(ii)(E), an employee must be offered a follow-up BeLPT within 30 days if the initial test result is anything other than normal, unless the employee has been confirmed positive (*e.g.,* if the initial BeLPT was performed on a split sample and showed two abnormal results). Thus, for example, if an employee's initial test result is abnormal, and the result of the follow-up testing offered to confirm the initial test result is abnormal or borderline, the employee would be confirmed positive. But if the result of the follow-up testing offered to confirm the initial abnormal test result

is normal, the employee is not confirmed positive. The initial abnormal result and a single abnormal or borderline result obtained from the next required BeLPT for that employee (typically, two years later) would not identify that employee as confirmed positive under this proposed modification. OSHA requests comments on the appropriateness of this proposed time period for obtaining BeLPT test samples that could be used to determine whether an employee is confirmed positive.

Examples of the potential types of results a worker may receive from BeLPT testing, including information obtained from split blood samples sent to separate labs or from a blood sample sent to a single lab, can be found in the docket (Document ID 0015).

OSHA is proposing to modify the standard's definition for *dermal contact with beryllium. Dermal contact with beryllium* appears in several places in the standard: Paragraph (f), Written exposure control plan; paragraph (h), Personal protective clothing and equipment (PPE); paragraph (i), Hygiene areas and practices; paragraph (k), Medical surveillance; and paragraph (m), Communication of hazards. Paragraph (b) currently defines *dermal contact with beryllium* as skin exposure to soluble beryllium compounds, beryllium solutions, or dust, fumes, or mists containing beryllium, where these materials contain beryllium in concentrations greater than or equal to 0.1 percent by weight. This definition was added to the standard through a direct final rule (83 FR 19936, 19940 (May 7, 2018)) following OSHA's promulgation of the final standard in January 2017. After publication of the 2017 final rule, stakeholders had raised questions about the meaning of *dermal contact with beryllium* where work processes involve materials with beryllium at very low concentrations. As a result of discussions with these stakeholders, OSHA added the definition to the general industry standard to clarify that *dermal contact with beryllium* means skin exposure to materials containing beryllium in concentrations greater than or equal to 0.1 percent by weight (83 FR at 19940).

OSHA is proposing to make two further changes to the definition of *dermal contact with beryllium.* First, OSHA proposes to add the term ''visible'' to the definition, so that the third form of dermal contact with beryllium would be skin exposure to visible dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight. Second, OSHA proposes to add a sentence to the definition specifying that handling beryllium materials in non-particulate solid form that are free from visible dust containing beryllium in concentrations greater than or equal to 0.1 percent by weight is not considered dermal contact with beryllium under the standard. OSHA believes that these proposed changes, in conjunction with other proposed changes (*e.g.,* the definition of a *beryllium work area*), would allow employers to more accurately identify areas where dermal contact with beryllium could be expected.

OSHA is proposing to add the term ''visible'' to clarify when skin exposure to beryllium-containing dust, fumes, or mist should be considered dermal contact with beryllium. Several of the standard's provisions are triggered where an employee has, or can be reasonably expected to have, dermal contact with beryllium. OSHA is concerned that, under the current definition, employers will be unable to accurately identify when dermal contact with beryllium has occurred, or should be reasonably expected to occur, for the purposes of compliance with this standard. Beryllium-generating processes can release beryllium in varying particle sizes and amounts, some of which are visible to the naked eye and some of which are not. OSHA is concerned that employers could reasonably interpret the provisions triggered by dermal contact with beryllium (*e.g.,* the use of PPE) as extending to every employee who could potentially encounter a minute and non-visible amount of beryllium particulate at its facility, irrespective of the employee's job duties and tasks. Such an interpretation would be contrary to OSHA's intent and could prompt employers to attempt infeasible compliance measures. OSHA believes that revising the definition is necessary to make the provisions triggered by dermal contact with beryllium understandable and workable.

OSHA believes that modifying the definition of *dermal contact with beryllium* to cover skin exposure to ''*visible* dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight'' may provide a clearer and more workable definition. The proposed change would allow employers to accurately identify the employees, and particularly those working outside of beryllium work areas or regulated areas, to whom the provisions triggered by dermal contact with beryllium apply, including the requirement to provide employees with PPE to protect against reasonably expected dermal contact with beryllium.

OSHA previously proposed using the visibility of beryllium contamination as a trigger for the use of PPE in the proposed rule that preceded the promulgation of the beryllium standard, based in part on the recommendations of a joint model standard that Materion and USW developed in 2012 (80 FR 47566 (Aug. 7, 2015)). That proposed rule would have required employers to provide appropriate PPE where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; where work clothing or skin may become visibly contaminated with beryllium; and where employees' skin is reasonably expected to be exposed to soluble beryllium compounds (80 FR at 47791–94).

In the final rule (82 FR 2470 (Jan. 9, 2017)), OSHA modified the provision based in part on comments from several public health experts who objected to using the phrase ''visibly contaminated.'' In particular, public health experts from NIOSH, National Jewish Health (NJH), and the American Thoracic Society, stated that beryllium can accumulate on the skin and on work surfaces without becoming visible, and beryllium sensitization can result from contact with small quantities of beryllium that are not visible to the naked eye (82 FR at 2679–80). Materion, on the other hand, supported using the phrase because relying on visual cues of contamination would make it easier for employers to comply with the PPE provision (82 FR at 2680).

OSHA ultimately agreed that skin contact with even small amounts of beryllium can cause beryllium sensitization and that triggering the use of PPE on visible contamination of the skin and clothing would not be sufficiently protective (82 FR at 2680–81). OSHA was concerned that employers might interpret the proposed ''may become visibly contaminated'' language as only requiring the use of PPE after work processes release quantities of beryllium sufficient to create deposits visible to the naked eye, by which time workers may have already had skin exposure sufficient to cause beryllium sensitization (82 FR at 2680). Employees should already be using PPE to prevent dermal contact by that time. Thus, to avoid the potential use of ''may become visibly contaminated'' as a lagging indicator triggering PPE, in the final rule the agency modified the provision to require the use of PPE wherever there is a ''reasonable expectation of dermal contact'' with beryllium (82 FR at 2680).

The current proposal continues to address this concern in two ways. First,

it retains the ''reasonable expectation'' trigger for PPE in the 2017 final rule. Thus, PPE use is required by the proposal before actual exposure occurs, accommodating the central concern of the final rule. Second, the location of the triggering exposure is changed. Where the original proposal required PPE where there may be visible accumulations of beryllium on skin or clothing, the current proposal requires PPE where there are visible dust, fumes, or mists containing beryllium in the work area that might come into contact with the skin. Therefore, in this way the current proposal triggers PPE before actual exposure occurs as well.

The current proposal also better addresses the practical aspects of a ''reasonable expectation'' trigger for PPE. OSHA's 2017 final rule did not address the practical aspects of complying with a trigger that required PPE when any dermal contact with beryllium might be reasonably expected. Although OSHA did not intend beryllium work areas to extend facility-wide, the 2017 final rule could nonetheless be read as effectively requiring employees to wear PPE facility-wide, even when not in proximity to beryllium generating processes (*e.g.,* administrative offices). Where an employer has a reasonable expectation that even very tiny amounts of non-trace beryllium dust, fume, or mist might spread outside of beryllium work areas, it may believe it is required to institute either a comprehensive wipe sampling program, or simply require all employees in the facility to wear PPE all of the time. OSHA did not explicitly cost the 2017 final rule as requiring PPE use to protect against dermal contact with non-visible beryllium dust, fumes, or mists outside of beryllium work areas, and OSHA is concerned that use of PPE in that circumstance is infeasible and unwarranted and would not meaningfully enhance worker protections. OSHA is therefore proposing the addition of a visual cue to enable employers to accurately identify the employees outside of beryllium work areas who need to wear PPE due to their reasonably-expected dermal contact with beryllium.

OSHA expects that the use of PPE will always be required in beryllium work areas because both the operations listed in Appendix A and those that can be reasonably expected to generate exposure at or above the action level would create a reasonable expectation of dermal contact with beryllium. This expectation is based, in part, on a study conducted by NIOSH and Materion and published in the Journal of Occupational and Environmental Hygiene. This study identified a strong correlation between airborne beryllium concentrations and the amount measured on gloves worn by workers at multiple beryllium facilities and jobs, indicating the potential for skin exposure where airborne beryllium is present (Document ID OSHA–H005C–2006–0870–0502). The expectation is also based on OSHA's review of data collected during site visits conducted by the agency that cover a wide range of processes (*e.g.,* furnace and melting operations, casting, grinding/deburring, machining and stamping) and a wide range of materials including beryllium composite, beryllium alloy, and beryllium oxide. The data show that those operations that would create a reasonable expectation of dermal contact, either through beryllium surface contamination or skin contamination, are covered either by proposed Appendix A or have exposures above the action level, (Document ID OSHA–H005C–2006–0870–0341). As such, both the provisions associated with beryllium work areas (listed above) and the provisions associated with dermal contact with beryllium would apply to employees in a beryllium work area (see Section II, Discussion of Proposed Changes, for the proposed revision to the definition of *dermal contact with beryllium*). OSHA requests comments on whether operations that trigger the creation of a beryllium work area also give rise to a reasonable expectation of dermal contact with beryllium within the beryllium work area. In light of the proposed change to the definition of *dermal contact with beryllium,* in which employees will have such contact if their skin is exposed to visible dusts, fumes, or mists that contain beryllium at the necessary concentration, OSHA also requests comment on whether processes exist that could trigger the creation of a beryllium work area, but could be reasonably expected to release only non-visible beryllium-containing dusts, fumes, or mists.

OSHA requests comment on all aspects of this discussion. In particular, OSHA is interested in learning about any alternative approaches that have been used to trigger PPE use and the basis for them. OSHA is also interested in learning of other reasonable ways to identify non-visible dermal exposures of concern outside of beryllium work areas. OSHA also requests information on the ways employers have implemented the PPE requirements of the current rule, including any difficulties they may have had in this regard.

OSHA notes that the record is unclear on whether facilities that process beryllium have any employees who work away from beryllium-releasing processes (*i.e.,* outside of beryllium work areas) but who could be reasonably expected to come into contact with solely non-visible particulates of beryllium in the course of their work. OSHA requests comment on whether such employees exist, and if so, whether the use of PPE would be necessary to adequately protect them from adverse health effects associated with beryllium exposure.

OSHA believes that the proposed change to the definition will likewise render more workable the additional provisions in the standard in which *dermal contact with beryllium* appears. For example, because it will help employers identify which employees have, or can be reasonably expected to have, dermal contact with beryllium, the proposed definition will allow employers to more accurately comply with the requirement in paragraph (f)(1)(i)(A) to establish, implement, and maintain a written exposure control plan that includes a list of operations and job titles reasonably expected to involve airborne exposure to or dermal contact with beryllium. OSHA expects that the list would likely include all operations and job titles in beryllium work areas, along with any additional operations or job titles for employees whose skin could be exposed to visible beryllium dust, fumes, or mists in concentrations of 0.1 percent by weight or more. Under the current definition, employers could reasonably interpret the standard as requiring them to list the job title for every employee at the facility who could come into contact with a minute and non-visible amount of beryllium particulate, including employees who do not work in proximity to beryllium-releasing processes (*e.g.,* in administrative offices). Adding a visual cue will allow employers to more accurately list the operations and job titles for employees who work outside of beryllium work areas and are reasonably expected to have dermal contact with beryllium. OSHA requests comment on whether this proposed change would cause an employer to omit any operations and job titles that should be included in the written exposure control plan, and whether it would reduce protections for any employees.

Similarly, the proposed definition will facilitate employer compliance with the requirement to provide information and training (in accordance with the Hazard Communication standard (29 CFR 1910.1200(h)) to each

employee who has, or can reasonably be expected to have, airborne exposure to or dermal contact with beryllium by the time of the employee's initial assignment and annually thereafter (paragraphs (m)(4)(i)(A)-(C)). The proposed definition would allow employers to accurately identify which employees must receive this information and training because they have, or can reasonably be expected to have, dermal contact with beryllium. OSHA expects that the employees who will be required to receive this training will include all employees who work in beryllium work areas as well as any other employees who may not be working directly with a beryllium-generating process, but may nonetheless reasonably be expected to have airborne exposure and/or skin contact with soluble beryllium, beryllium solutions, or visible beryllium dust, fumes, or mists in concentrations of 0.1 percent by weight or more. As discussed previously, OSHA intends the proposed modification to the definition of *dermal contact with beryllium* to provide employers with a workable measure for determining which employees outside of beryllium work areas and regulated areas should receive this information and training. OSHA requests comment on whether this proposed change would still capture all of the employees that would benefit from the training required under this standard.

Because the change would allow employers to more accurately identify the employees who have had dermal contact with beryllium, the proposed definition would also facilitate proper compliance with paragraph (i)(1)(ii), which requires employers to ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. The addition of the term ''visible'' to the definition would prevent employers from speculating that all employees in a facility, including those employees who do not work near beryllium-releasing processes (*e.g.,* administrative employees), must wash their exposed skin because they might have come into contact with non-visible beryllium particulate. Such an interpretation would be contrary to OSHA's intent and could be infeasible in practice. As stated above, it is unclear from the existing record whether there are employees who work exclusively outside of beryllium work areas but who could come into contact with solely *non-visible* beryllium particulate during their work and yet not be required to wash their exposed skin under the proposed rule. OSHA requests comment on whether such employees exist, and whether this proposed change would reduce protections for any employees.

The proposed definition would further improve employer compliance with the requirements in paragraph (k) to offer employees a medical examination including a medical and work history that emphasizes past and present airborne exposure to or dermal contact with beryllium (paragraph (k)(3)(ii)(A)), and to provide the examining physician or other licensed health care professional (PLHCP) (and the agreed-upon CBD diagnostic center, if such an evaluation is required) with a description of the employee's former and current duties that relate to the employee's airborne exposure to and dermal contact with beryllium (paragraph (k)(4)(i)). Because it would improve employers' ability to identify when dermal contact with beryllium has occurred or could occur, this change would permit employers to accurately complete employee medical and work histories and the reports that they must provide to examining PLHCPs or CBD diagnostic centers. Similar to the change's effect on the provisions discussed above, adding the term ''visible'' would prevent employers from including superfluous information in these medical and work histories and reports because they are concerned that an employee might have conceivably come into contact with solely non-visible beryllium particulate outside of a beryllium work area. Such an expansive interpretation would be contrary to OSHA's intent. OSHA requests comment on whether this change would cause employers to omit needed information from these medical and work histories and reports, and, as a result, undermine the effectiveness of the medical examinations.

Dermal contact with beryllium is also currently mentioned in the requirement in paragraph (f)(1)(ii)(B) that employers update their written exposure control plans when notified that an employee shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium. But as explained in the summary and explanation for proposed changes to paragraph (f), OSHA is proposing to remove the reference to dermal contact with beryllium in that provision so that it would require employers to update exposure control plans when they are notified that an employee shows signs or symptoms associated with *any* exposure to beryllium. If that proposed change to paragraph (f)(1)(ii)(B) is finalized, the proposed change to the definition of *dermal contact with beryllium* will have no effect on that provision. Even if the proposed change to paragraph (f)(1)(ii)(B) is not finalized, however, OSHA does not anticipate that the proposed change to the definition of *dermal contact with beryllium* would have any meaningful impact on that requirement because the signs and symptoms of dermal contact with beryllium are the same regardless of whether the beryllium is visible (82 FR at 2680–81).

Dermal contact with beryllium also currently appears in paragraph (h)(3)(iii). That provision requires employers to inform in writing persons or business entities who launder, clean, or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the personal protective clothing and equipment must be handled in accordance with the standard. As explained below, OSHA is proposing to revise that provision so that it requires employers to inform launderers, cleaners, and repairers of the potentially harmful effects of all exposure to beryllium (see discussion of proposed changes to paragraph (h) later in this section). If the proposed revision to this paragraph is not finalized, the proposed change to the definition of *dermal contact with beryllium* would still have no impact because the effects of skin contact with beryllium are the same regardless of whether the beryllium is visible (82 FR at 2680–81).

OSHA is also proposing to add two additional references to dermal contact with beryllium in paragraph (i), Hygiene areas and practices, to account for additional proposed changes to the definition of *beryllium work area* in paragraph (b). Paragraph (i) includes requirements for employers to provide each employee working in a beryllium work area with readily accessible washing facilities (paragraph (i)(1)(i)) and a designated change room where employees are required to remove their personal clothing (paragraph (i)(2)). But, as explained earlier in this section, OSHA is proposing to revise the definition of *beryllium work area* so that it no longer refers to the potential for dermal contact with beryllium.

OSHA intends for the requirements to provide washing facilities and change rooms to apply to employees who can reasonably be expected to have dermal contact with beryllium, regardless of whether they work in a beryllium work area as defined in this proposal. As discussed above, there may be

employees outside of the beryllium work area that may have a reasonable expectation of dermal contact with beryllium. Therefore, OSHA is proposing to add two additional references to dermal contact with beryllium to paragraph (i). First, OSHA is proposing to revise paragraph (i)(1) so that the requirements would apply to each employee who works in a beryllium work area or who can reasonably be expected to have dermal contact with beryllium. Paragraph (i)(1)(i) would then require employers to provide washing facilities to all employees who can be reasonably expected to have dermal contact with beryllium. Second, OSHA is proposing to revise paragraph (i)(2) so that employers are required to provide change rooms to employees who are required to use personal protective clothing or equipment under paragraph (h)(1)(ii), if those employees are required to remove their personal clothing. Because paragraph (h)(1)(ii) requires the use of PPE where there is a reasonable expectation of dermal contact with beryllium, this proposed change would ensure that, if OSHA finalizes the proposed changes to the definition of *beryllium work area,* the requirement for change rooms would continue to protect those employees who can reasonably be expected to have dermal contact with beryllium.

As discussed above, it is unclear from the existing record whether there are employees working outside of beryllium work areas who could come into contact with solely *non-visible* beryllium particulate, whose exposure would not trigger the employer's obligation to provide washing facilities and change rooms under this proposal. OSHA requests comment on whether such employees exist, and if so, whether the use of washing facilities is necessary to adequately protect them from adverse health effects associated with beryllium exposure.

The second change that OSHA is proposing to the definition of *dermal contact with beryllium* is to add a sentence specifying that handling of beryllium materials in non-particulate solid form that are free from visible dust containing beryllium in concentrations greater than or equal to 0.1 percent by weight is *not* considered ''dermal contact with beryllium'' under the standard. OSHA explained in the final rule that beryllium-containing solid objects, or ''articles,'' with uncompromised physical integrity are unlikely to release beryllium that would pose a health hazard for workers (82 FR at 2640). Accordingly, paragraph (a)(2) states that the beryllium standard's provisions do not apply to the specified articles that the employer does not process.

The proposed addition to the definition of *dermal contact with beryllium* would clarify that the provisions in the standard related to dermal contact with beryllium do not apply to the handling of solid beryllium-containing objects that the employer does not process, unless visible beryllium particulate has contaminated the surface of the object. As discussed above, in areas where the employer reasonably expects that employees' skin will be exposed to visible beryllium dust, fumes, or mists, including those that may have contaminated the surface of solid objects, employers would be required to provide, and ensure that employees use, appropriate PPE. Outside of areas where an employer reasonably expects that visible dust, fumes, or mists may be present, such as beryllium work areas, the use of PPE would not be required, and the provisions requiring employers to minimize surface beryllium in paragraph (i) and paragraph (j) of the standard should sufficiently protect employees from contact with beryllium-contaminated objects. OSHA requests comments on these proposed changes. OSHA particularly requests comments on whether it is appropriate to trigger protections that apply to dermal contact with beryllium on skin exposure to dusts, fumes, or mists only if they are visible, and whether this will sufficiently protect employees from exposure to accumulations of beryllium particulate that are not visible to the naked eye but that could cause beryllium sensitization. OSHA also requests comments on whether there are alternative approaches to revising the definition of *dermal contact with beryllium* that would enhance employer understanding and improve compliance with the provisions in the standard that are triggered by actual or reasonably expected dermal contact with beryllium, while maintaining safety and health protections for workers.

B. Written Exposure Control Plan

Paragraph (f)(1) of the beryllium standard for general industry (29 CFR 1910.1024(f)(1)) addresses the written exposure control plan that the employer must establish, implement, and maintain. Paragraph (f)(1)(i) specifies the information that must be included in the plan and paragraph (f)(1)(ii) addresses the requirements for employers to review each plan at least annually and update it under specified circumstances.

OSHA is proposing two wording changes to these provisions. Paragraph (f)(1)(i)(D) addresses procedures for minimizing cross-contamination within beryllium work areas. This includes the transfer of beryllium between surfaces, equipment, clothing, materials, and articles. This proposal would remove the word ''preventing'' from the text to clarify that these procedures may not totally eliminate the transfer of beryllium, but should minimize cross-contamination of beryllium, including between surfaces, equipment, clothing, materials, and articles.

Paragraph (f)(1)(ii)(B) specifies that when an employer is notified that an employee is eligible for medical removal, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with airborne exposure to or dermal contact with beryllium, the employer must update the written exposure control plan as necessary. OSHA is proposing to replace the phrase ''airborne exposure to and dermal contact with beryllium'' with ''exposure to beryllium.'' This would simplify the language of the provision while still capturing all potential exposure scenarios currently covered. Because these proposed changes are merely clarifying, OSHA expects they would maintain safety and health protections for workers.

C. Personal Protective Clothing and Equipment

OSHA is proposing two revisions to paragraph (h) of the beryllium standard for general industry, personal protective clothing and equipment (29 CFR 1910.1024(h)). The first proposed revision relates to paragraph (h)(2)(i), which addresses removal and storage of personal protective clothing and equipment (PPE). This provision requires employers to ensure that each employee removes all beryllium-contaminated PPE at the end of the work shift, at the completion of tasks involving beryllium, or when PPE becomes visibly contaminated with beryllium, whichever comes first. OSHA is proposing to modify the phrase ''at the completion of tasks involving beryllium'' in paragraph (h)(2)(i) by changing ''tasks'' to ''all tasks.''

This revision would clarify the trigger for when employees must remove beryllium-contaminated PPE. OSHA's intent, expressed in the final rule, is that PPE contaminated with beryllium should not be worn when tasks involving beryllium exposure have been completed for the day (82 FR 2682). Thus, when employees perform multiple tasks involving beryllium successively or intermittently

throughout the day, the employer must ensure that each employee removes all beryllium-contaminated PPE at the completion of the set of tasks involving beryllium, not necessarily after each separate task. If, however, employees perform tasks involving beryllium exposure for only the first two hours of a work shift, and then perform tasks that do not involve exposure to beryllium, the employer must ensure that employees remove their PPE after the beryllium exposure period. Unless the PPE becomes visibly contaminated with beryllium, OSHA does not intend this provision to require continuous PPE changes throughout the work shift. The proposed revision would clarify OSHA's intent.

Paragraph (h)(3)(iii) requires the employer to inform in writing the persons or the business entities who launder, clean or repair the PPE required by this standard of the potentially harmful effects of airborne exposure to and dermal contact with beryllium and that the PPE must be handled in accordance with this standard. OSHA is proposing to replace the phrase ''airborne exposure to and dermal contact with beryllium'' with ''exposure to beryllium.'' This would simplify the language of the provision while still capturing all potential exposure scenarios currently covered. An identical language change is being proposed in the methods of compliance paragraph, (f)(1)(ii)(B). Because these changes would merely clarify OSHA's original intent for these provisions of the standard, the agency anticipates that the proposed revisions to paragraph (h) would maintain safety and health protections for workers.

D. Hygiene Areas and Practices

OSHA is proposing three changes to paragraph (i) of the general industry standard, Hygiene areas and practices (29 CFR 1910.1024(i)). This paragraph requires that the employer provide employees with readily accessible washing facilities, change rooms, and showers when certain conditions are met; requires the employer to take certain steps to minimize exposure in eating and drinking areas; and prohibits certain practices that may contribute to beryllium exposure. OSHA is proposing the first two changes, which apply to paragraphs (i)(1) and (i)(2), to maintain the protections included in these paragraphs for employees who have dermal contact with beryllium if the proposed change to the definition of beryllium work area, discussed previously in this Summary and Explanation, is finalized. OSHA is proposing the third change, which applies to paragraph (i)(4), to clarify the requirements for cleaning beryllium-contaminated PPE prior to entering an eating or drinking area.

As explained in the previous discussion of proposed changes to the definition of *beryllium work area,* OSHA is proposing several changes to the definition of *beryllium work area* to clarify where a beryllium work area should be established. One of the changes proposed is to remove dermal contact with beryllium as one of the triggers that would require an employer to establish a beryllium work area. If this proposed change to the definition of *beryllium work area* is finalized, it is OSHA's intention that the hygiene provisions related to washing facilities and change rooms will still apply to employees who can reasonably be expected to have dermal contact with beryllium regardless of whether they work in beryllium work areas as defined in the revised definition. OSHA accordingly proposes two changes.

First, OSHA is proposing a change in the wording of paragraph (i)(1). As currently written, paragraph (i)(1) requires that, for each employee working in a beryllium work area, the employer must provide readily accessible washing facilities in accordance with the beryllium standard and the Sanitation standard (29 CFR 1910.141) to remove beryllium from the hands, face, and neck. The employer must also ensure that employees who have dermal contact with beryllium wash any exposed skin at the end of the activity, process, or work shift and prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet. OSHA is proposing to apply the requirements of paragraph (i)(1) to each employee who can reasonably be expected to have dermal contact with beryllium in addition to each employee working in a beryllium work area. This proposed change would ensure that, if OSHA finalizes a definition of *beryllium work area* that does not require employers to establish a beryllium work area where there is potential for dermal contact with beryllium, the requirement for washing facilities would continue to protect those employees who are reasonably expected to have dermal contact with beryllium, consistent with OSHA's original intent. Thus, under the proposed change, the employer still would be required to provide readily accessible washing facilities to all employees with reasonably expected dermal contact in accordance with paragraph (i)(1)(i) and ensure that all such employees wash exposed skin in accordance with paragraph (i)(1)(ii).

Second, OSHA is proposing a change in the wording of paragraph (i)(2). As currently written, paragraph (i)(2) requires that, for employees who work in a beryllium work area, the employer must provide a designated change room in accordance with the beryllium standard and the Sanitation standard (29 CFR 1910.141) where employees are required to remove their personal clothing. OSHA is proposing to apply the requirements of paragraph (i)(2) to employees who are required to use personal protective clothing or equipment under paragraph (h)(1)(ii) of the beryllium standard, instead of to employees who work in a beryllium work area. Paragraph (h)(1)(ii) of the beryllium standard requires the provision and use of appropriate PPE ''[w]here there is a reasonable expectation of dermal contact with beryllium.'' This proposed change would ensure that, if OSHA finalizes a definition of *beryllium work area* that does not require employers to establish a beryllium work area where there is potential for dermal contact with beryllium, the requirement for change rooms would continue to protect those employees who are reasonably expected to have dermal contact with beryllium, consistent with OSHA's original intent.

OSHA is also proposing a third change, which applies to paragraph (i)(4), in order to clarify the requirements for cleaning beryllium-contaminated PPE prior to entering an eating or drinking area. Paragraph (i)(4)(ii) of the beryllium standard for general industry (29 CFR 1910.1024(i)(4)(ii)) requires the employer to ensure that no employees enter any eating or drinking area with beryllium-contaminated personal protective clothing or equipment unless, prior to entry, surface beryllium has been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body. OSHA is proposing to modify this paragraph to require the employer to ensure that, before employees enter an eating or drinking area, beryllium-contaminated PPE is cleaned, as necessary, to be as free as practicable of beryllium by methods that do not disperse beryllium into the air or onto an employee's body. This proposed change would clarify that OSHA does not expect the methods used to clean PPE prior to entering an eating or drinking area to completely eliminate residual beryllium from the surface of the PPE if complete elimination is not practicable. This is consistent with OSHA's determination, expressed in the preamble to the final rule, that ''as free

as practicable'' is ''the most appropriate terminology for requirements pertaining to surface cleanliness'' (82 FR 2687). This proposed clarification also aligns the language of paragraph (i)(4)(ii) with the language of paragraph (i)(4)(i), which requires employers to ensure that beryllium-contaminated surfaces in eating and drinking areas are as free as practicable of beryllium. Finally, requiring cleaning only ''as necessary'' would clarify that cleaning would not be required if the PPE is already as free as practicable of beryllium. OSHA expects these proposed changes to paragraph (i) would maintain safety and health protections for workers.

E. Disposal and Recycling

Paragraph (j)(3) of the beryllium standard for general industry (29 CFR 1910.1024(j)(3)) addresses disposal and recycling of materials that contain beryllium in concentrations of 0.1 percent by weight or more or that are contaminated with beryllium. That paragraph currently specifies that (1) materials designated for disposal must be disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled according to paragraph (m)(3) of the beryllium standard, and (2) materials designated for recycling must be cleaned to be as free as practicable of surface beryllium contamination and labeled according to paragraph (m)(3), or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled according to paragraph (m)(3). The requirements do not apply to materials containing only trace amounts of beryllium (less than 0.1 percent by weight).

OSHA is proposing several changes to these provisions. Generally, OSHA is proposing that provisions pertaining to recycling and disposal also address reuse because in some cases workers may be exposed to materials containing or contaminated with beryllium that are directly reused without first being recycled into a different form. For example, a manufacturer may sell a by-product from a process to a downstream manufacturer that would reuse the by-product as a component of a new product. Recycling, on the other hand, typically involves the further processing of waste materials to separate and recover various components of value. OSHA is also proposing some minor changes in terminology and organization to improve the clarity and internal consistency of the standard.

Proposed paragraph (j)(3) would be reorganized into three subparagraphs and would identify that the provisions address reuse in addition to disposal and recycling. Proposed paragraph (j)(3)(i) would require employers to ensure that materials containing at least 0.1% beryllium by weight or contaminated with beryllium that are transferred to another party for disposal, recycling, or reuse are labeled according to paragraph (m)(3) of the standard. This reorganization of the provisions would make it clear that the labeling requirements under paragraph (m)(3) apply regardless of whether the employer transfers materials to another party for disposal, recycling, or reuse. Including that information in paragraph (j)(3)(i) avoids the need to repeat the information in paragraph (j)(3)(ii), which addresses disposal specifically, and paragraph (j)(3)(iii), which addresses recycling and reuse.

Proposed paragraph (j)(3)(ii) would require that with the exception of intra-plant transfers, materials designated for disposal that contain at least 0.1% beryllium by weight or are contaminated with beryllium be cleaned to be as free as practicable of beryllium or placed in enclosures, such as bags or containers, that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport. Proposed paragraph (j)(3)(iii) would require that with the exception of intra-plant transfers, materials designated for recycling or reuse that contain at least 0.1% beryllium by weight or are contaminated with beryllium be cleaned to be as free as practicable of beryllium or placed in enclosures, such as bags or containers, that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport.

The proposed addition of the term ''except for intra-plant transfers'' to proposed paragraphs (j)(3)(ii) and (iii) clarifies that the requirements in paragraph (j)(3) do not apply to transfers within a plant. As discussed in the preamble for the beryllium final rule (82 FR 2470, 2696), OSHA did not intend the provisions of paragraph (j)(3) of the general industry standard to require employers to clean or enclose materials to be used in another location of the same facility. Since the disposal and recycling provisions would now also address reuse under this proposal, this proposed change would make OSHA's intent explicit. Under other provisions of the beryllium standard, employers would still be required to communicate possible hazards to employees and protect employees who may be exposed to those materials during intra-plant transfer.

OSHA is also proposing that the phrase ''materials that contain beryllium in concentrations of 0.1 percent by weight or more'' be replaced with the phrase ''materials that contain at least 0.1 percent beryllium by weight'' in paragraphs (j)(3)(i)–(iii). The change in terminology is to simplify the language and does not change the meaning.

The requirement in proposed paragraphs (j)(3)(ii) and (iii) that materials not otherwise cleaned be placed in enclosures that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport clarifies the requirement from the final standard that the materials be placed in ''sealed, impermeable enclosures.'' As discussed in the preamble to the final standard (82 FR 2470, 2695), OSHA disagreed with stakeholders who found the requirement for sealed, impermeable enclosures to be ''problematically vague.'' As the agency explained, ''OSHA intends this term to be broad and the provision performance-oriented, so as to allow employers in a variety of industries flexibility to decide what type of enclosures (*e.g.,* bags or other containers) are best suited to their workplace and the nature of the beryllium-containing materials they are disposing or designating for reuse outside the facility.'' Further, the term ''impermeable'' was not intended to mean absolutely impervious to rupture; rather, OSHA explained that the enclosures should be impermeable to the extent that they would not allow materials to escape ''under normal conditions of use.''

Since the promulgation of the final rule in 2017, OSHA has learned from stakeholders that further clarification may help eliminate confusion regarding what types of enclosures would be acceptable under the standard. Thus, the proposed change makes explicit what had been intended in the 2017 final rulemaking. In addition, the proposed change would reinforce the requirement that employers select the appropriate type of container to prevent release based on the form of beryllium and how it is normally handled. For example, a container that prevents the release of a beryllium particulate may not be effective in preventing the release of a beryllium solution.

Proposed paragraphs (j)(3)(ii) and (iii) would also clarify the cleaning requirements of the beryllium standard by removing the phrase ''of surface beryllium contamination,'' which may cause confusion because the term ''surface beryllium contamination'' does not appear in other provisions of the standard and is not defined in the beryllium standard. Elsewhere in the standard, OSHA uses the phrase ''as free as practicable of beryllium.'' OSHA has

discussed the meaning of this phrase in the summary and explanation of paragraph (j) in the 2017 final rule (82 FR 2690), as well as previously in a 2014 letter of interpretation explaining the phrase in the context of the agency's standard for hexavalent chromium (OSHA, Nov. 5, 2014, Letter of Interpretation, available at *https://www.osha.gov/laws-regs/standardinterpretations/2014-11-05*). OSHA believes the phrase ''as free as practicable of beryllium'' will more clearly convey the cleaning requirements under the beryllium standard than the phrase ''as free as practicable of surface beryllium contamination.''

Finally, proposed paragraph (j)(3)(ii) would allow the same options for either cleaning or enclosure found in the recycling and reuse requirements for materials designated for disposal. The beryllium standard currently does not include an option of cleaning materials designated for disposal and instead requires enclosure in containers. Since the promulgation of the beryllium final rule in 2017, OSHA has learned from stakeholders that in some cases, items that contain or are contaminated with beryllium may not be suitable for enclosure prior to disposal. While OSHA agreed with ORCHSE Strategies in 2017 that municipal and commercial disposal workers should be protected from exposure to beryllium from contact with materials discarded from beryllium work areas in general industry by placing those materials in enclosed containers (82 FR 2695; Document ID OSHA–H005C–2006–0870–1691, p. 5), the agency had not considered situations where it would be impractical to require enclosure because the materials in question were large items such as machines or structures that may contain or be contaminated with beryllium, rather than more common items, such as beryllium scrap metal or shavings. For example, a machine that was used to process beryllium-containing materials may be contaminated with beryllium. Enclosing the machine in a large container prior to disposal would be less practical, and no more effective, than cleaning the machine to be as free as practicable of beryllium contamination prior to disposal. Thus, OSHA has preliminarily determined that workers handling items designated for disposal, like workers handling items designated for recycling or reuse, will be just as protected from exposure to beryllium if the items are cleaned to be as free as practicable of beryllium as if the items were placed in containers. Regardless of whether an employer chooses to clean or enclose materials designated for disposal, the labeling requirements under proposed paragraph (j)(3)(i) would still apply and would require the materials designated for disposal to be labeled in accordance with paragraph (m)(3) of this standard. OSHA expects these proposed changes to paragraph (j) to maintain safety and health protections for workers.

F. Medical Surveillance

Paragraph (k) of the beryllium standard for general industry (29 CFR 1910.1024) addresses medical surveillance requirements. OSHA is proposing changes to two medical surveillance provisions.

Under paragraph (k)(2)(i)(B), the employer must provide a medical examination within 30 days after determining that the employee shows signs or symptoms of CBD or other beryllium-related health effects or that the employee has been exposed to beryllium in an emergency. OSHA proposes removing the requirement for a medical examination within 30 days of exposure in an emergency and adding paragraph (k)(2)(iv), which would require the employer to offer a medical examination at least one year after but no more than two years after the employee is exposed to beryllium in an emergency. OSHA has preliminarily determined that the requirement to provide a medical examination between one and two years after exposure in an emergency is more appropriate than a 30-day requirement and would enhance worker protections.

In the proposal for the 2017 beryllium rule (80 FR 47798, Summary and Explanation for proposed paragraph (k)(2)(i)(B)), OSHA proposed requiring employers to provide medical examinations to employees exposed to beryllium during an emergency, and to those showing signs or symptoms of CBD, within 30 days of the employer becoming aware that these employees met those criteria. During the public comment period for that NPRM, OSHA did not receive any comments from stakeholders about the time period to offer medical examinations following a report of symptoms or exposure in an emergency. The agency determined the 30-day trigger to be administratively convenient for post-emergency surveillance, because it is consistent with other OSHA standards and with other triggers in the beryllium standards (82 FR 2702, Summary and Explanation for paragraph (k)(2)(i)(B)). OSHA therefore retained paragraph (k)(2)(i)(B), as proposed, in the final rule.

After publication of the final rule, stakeholders suggested to OSHA that sensitization might not be detected within 30 days after exposure in individuals who may become sensitized, so a longer timeframe for medical examinations may be more appropriate. OSHA acknowledges uncertainty regarding the time period in which sensitization may occur following a one-time exposure to a significant concentration of beryllium (*i.e.,* exposures exceeding the PEL) in an emergency. Further, as discussed in the final rule (82 FR 2530, 2533), OSHA found that beryllium sensitization can occur several months or more after initial exposure to beryllium among workers with regular occupational exposure to beryllium.

Because sensitization might not be detected within 30 days after exposure in individuals who may become sensitized, OSHA believes the proposed time period of one to two years may be more likely to enable detection of sensitization in employees in the first test following exposure in an emergency. OSHA notes that, if an employee exposed during an emergency were to become sensitized and develop signs or symptoms of CBD prior to one year after exposure in an emergency, the employer would still be required to provide that employee a medical examination under paragraph (k)(2)(i)(B) of the standard. Further, OSHA does not intend this revision to preclude employers from voluntarily providing a medical examination within the first year after an emergency. However, providing a medical examination sooner would not relieve an employer of the duty to provide an exam in the one- to two-year window. For those employees who are already eligible for periodic medical surveillance, the examination for the emergency exposure could be scheduled to coincide with the next periodic examination that is within two years of the last periodic medical examination and at least one but no more than two years after the emergency exposure, satisfying the requirements of both paragraphs (k)(2)(ii) and (iv).

OSHA requests comment on the appropriateness of the change from requiring a medical examination within 30 days following an employer's determination that an employee has been exposed in an emergency to between one and two years following such exposure. Specifically, is a time frame of at least one year but not more than two years appropriate, or are there immediate health effects that would support providing an examination before one year following the emergency? What is the ideal timeframe to offer a medical examination following

exposure in an emergency to address sensitization or other health effects?

As promulgated, paragraph (k)(2)(i)(B) currently requires the employer to provide a medical examination within 30 days after the employer determines that an employee has been exposed to beryllium in an emergency. Under proposed paragraph (k)(2)(iv), the time period for providing a medical examination begins to run from the date the employee is exposed during an emergency, regardless of when the employer discovers that the exposure occurred. Because under this proposal the medical examination will not occur until at least a year from the date of the exposure in an emergency, and because OSHA believes that employers typically will learn of the emergency resulting in exposure immediately or soon after it occurs, OSHA has preliminarily determined that it is appropriate to measure the time period from the date of exposure. OSHA requests comments on the appropriateness of calculating the time period for a medical examination from the occurrence of the emergency rather than from the employer's determination of eligibility.

Paragraph (k)(7)(i) currently requires that the employer provide, at no cost to the employee, an evaluation at a CBD diagnostic center that is mutually agreed upon by the employee and employer within 30 days of the employer receiving one of the types of documentation listed in paragraph (k)(7)(i)(A) or (B). OSHA is proposing a change to paragraph (k)(7)(i) to account for the proposed revision to the definition of *CBD diagnostic center* discussed earlier in this proposal. As discussed in more detail above, the current definition of *CBD diagnostic center* requires that the evaluation at the CBD diagnostic center include a pulmonary function test as outlined by American Thoracic Society (ATS) criteria, bronchoalveolar lavage (BAL), and transbronchial biopsy. OSHA proposes amending the definition to indicate that a CBD diagnostic center must be capable of performing those tests, but need not necessarily perform all tests during all evaluations. Nonetheless, OSHA intends that the employer provide those tests if deemed appropriate by the examining physician at the CBD diagnostic center.

Accordingly, OSHA proposes expanding paragraph (k)(7)(i) to require that the employer provide, at no cost to the employee and within a reasonable time after consultation with the CBD diagnostic center, any of the following tests if deemed appropriate by the examining physician at the CBD diagnostic center: A pulmonary function test as outlined by ATS criteria; BAL; and transbronchial biopsy. The proposed changes would ensure that the employee receives those tests recommended by the examining physician and receives them at no cost and within a reasonable time. In addition, the revision would clarify OSHA's original intent that, instead of requiring all tests to be conducted after referral to a CBD diagnostic center, the standard would allow the examining physician at the CBD diagnostic center the discretion to select one or more of those tests as appropriate. OSHA further notes that, by requiring the employer to provide those tests recommended by the examining physician at the CBD diagnostic center that was previously agreed-upon by the employer and employee, OSHA intends those tests to be provided by the same CBD diagnostic center unless the employer and employee agree to a different CBD diagnostic center. OSHA expects this proposed revision to maintain safety and health protections for workers.

In the proposal for the 2017 beryllium rule, OSHA proposed to require a consultation between the employee and the licensed physician within 30 days of the employee being confirmed positive to discuss a referral to a CBD diagnostic center, but there was no time limit for the employer to provide the evaluation at the CBD diagnostic center (80 FR 47800, Summary and Explanation for proposed paragraph (k)(6)(i) and (ii)). In the final rule, OSHA altered this requirement, now in paragraph (k)(7)(i), to require that the examination at the CBD diagnostic center be provided within 30 days of the employer receiving one of the types of documentation listed in paragraph (k)(7)(i)(A) or (B). The purpose of this 30-day requirement was to ensure that employees receive the examination in a timely manner. This time period is also consistent with other OSHA standards.

However, since OSHA published the final rule, stakeholders have raised concerns that scheduling the appropriate tests with an examining physician at the CBD diagnostic center may take longer than 30 days, making compliance with this provision difficult. To address this concern, OSHA is proposing that the employer provide an initial consultation with the CBD diagnostic center, rather than the full evaluation, within 30 days of the employer receiving one of the types of documentation listed in paragraph (k)(7)(i)(A) or (B). OSHA believes that such a consultation could be scheduled with a physician within 30 days and could be provided by telephone or by virtual conferencing methods. Providing a consultation before the full examination at the CBD diagnostic center demonstrates that the employer has made an effort to begin the process for a medical examination. It also allows the employee to consult with a physician to discuss concerns and ask questions while waiting for a medical examination. This consultation would allow the physician to explain the types of tests that are recommended based on medical findings about the employee and the risks and benefits of undergoing such testing. Although this proposed change would allow the employer more time to provide the full evaluation, the proposed requirement to provide any recommended tests within a reasonable time after the initial consultation would ensure that the employer secures an appointment for the evaluation in a timely manner. And this proposed change would not prohibit the employer from providing both the consultation and the full evaluation at the same appointment, as long as the appointment is within 30 days of the employer receiving one of the types of documentation listed in paragraph (k)(7)(i)(A) or (B).

OSHA requests comments on this change, and specifically requests comment on whether it is appropriate to require the employer to provide a consultation with the CBD diagnostic center, rather than the full evaluation, within 30 days. OSHA also requests comment on whether a consultation via telephone or virtual conferencing methods is sufficient or whether it is appropriate to require the employer to provide an in-person consultation upon the employee's request.

G. Hazard Communication

OSHA is also proposing changes to paragraph (m), communication of hazards, of the beryllium standard for general industry (82 FR 2470). This provision sets forth the employer's obligations to comply with OSHA's Hazard Communication Standard (HCS) (29 CFR 1910.1200) relative to beryllium and to take additional steps to warn and train employees about the hazards of beryllium.

Paragraph (m)(3) addresses warning label requirements. This paragraph requires the employer to label each bag and container of clothing, equipment, and materials contaminated with beryllium, and specifies the precise wording on the label. OSHA is proposing to modify the language in paragraph (m)(3) to remove the words ''bag and'' and insert the descriptive adjective ''immediate'' to clarify that the employer need only label the immediate container of beryllium-contaminated

items. OSHA is proposing this change to be consistent with the HCS regarding bags or containers within larger containers. Under the HCS, only the primary or immediate container must be labeled and not the larger container holding the labeled bag or container. See 29 CFR 1910.1200(c) (definition of ''Label''). This change would effectuate OSHA's intent, expressed in the final rule, that the hazard communication requirements of the beryllium standard ''be substantively as consistent as possible'' with the HCS (82 FR 2724). It would therefore maintain safety and health protections for workers.

Paragraph (m)(4)(ii)(A) addresses employee information and training and requires the employer to ensure that each employee exposed to airborne beryllium can demonstrate knowledge and understanding of the health hazards associated with airborne exposure to and contact with beryllium, including the signs and symptoms of CBD. OSHA is proposing to modify the language in paragraph (m)(4)(ii)(A) by adding the word ''dermal'' to contact with beryllium. This revision would clarify OSHA's intent that employers must ensure that exposed employees can demonstrate knowledge and understanding of the health hazards caused by dermal contact with beryllium.

Similarly, paragraph (m)(4)(ii)(E) addresses employee information and training and requires the employer to ensure that each employee exposed to airborne beryllium can demonstrate knowledge and understanding of measures employees can take to protect themselves from airborne exposure to and contact with beryllium, including personal hygiene practices. OSHA is proposing to modify the language in paragraph (m)(4)(ii)(E) by adding the word ''dermal'' to contact with beryllium. This revision would clarify OSHA's intent that employers must ensure exposed employees can demonstrate knowledge and understanding of measures employees can take to protect themselves from dermal contact with beryllium. OSHA expects these proposed changes would maintain safety and health protections for workers.

H. Recordkeeping

OSHA is proposing to modify paragraph (n), Recordkeeping, by removing the requirement to include each employee's Social Security Number (SSN) in the air monitoring data ((n)(1)(ii)(F)), medical surveillance ((n)(3)((ii)(A)), and training ((n)(4)(i)) provisions.

The 2015 beryllium NPRM proposed to require inclusion of the employee's SSN in records related to air monitoring, medical surveillance, and training, similar to provisions in previous substance-specific health standards. As OSHA explained in the 2017 beryllium final rule, using an employee's SSN is a useful tool for evaluating an individual's exposure over time because an SSN is unique to an individual, is retained for a lifetime, and does not change when an employee changes employers (82 FR 2730). OSHA received several objections to the proposed requirement, citing employee privacy and identity theft concerns. OSHA recognized the privacy concerns expressed by commenters regarding this requirement, but concluded that the beryllium rule should adhere to the agency's past consistent practice of requiring an employee's SSN on records, and that any change to this requirement should be comprehensive and apply to all OSHA standards, not just the standards for beryllium (82 FR 2730). In 2016, OSHA proposed to delete the requirement that employers include SSNs in records required by its substance-specific standards in the agency's Standards Improvement Project-Phase IV (SIP–IV) proposed rule (81 FR 68504, 68526–68528 (10/4/16)). Consistent with the SIP–IV proposal, OSHA is now proposing to modify the beryllium standard for general industry by removing the requirement to include SSNs in the recordkeeping provisions in paragraphs (n)(1)(ii)(F) (air monitoring data), (n)(3)((ii)(A) (medical surveillance), and (n)(4)(i) (training).

This proposed change would not require employers to delete employee SSNs from existing records. It would also not mandate a specific type of identification method that employers should use on newly-created records, but would instead provide employers with the flexibility to develop systems that best work for their unique situations. Therefore, employers would have the option to continue to use SSNs as employee identifiers for their records or to use an alternative employee identifier system. OSHA expects this proposed change would maintain safety and health protections for workers.

III. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970 (''the OSH Act'' or ''the Act''), 29 U.S.C. 651 *et seq.,* is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate occupational safety and health standards pursuant to notice and comment rulemaking. See 29 U.S.C. 655(b). An occupational safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.'' 29 U.S.C. 652(8).

The Act also authorizes the Secretary to ''modify'' or ''revoke'' any occupational safety or health standard, 29 U.S.C. 655(b), and under the Administrative Procedure Act, regulatory agencies generally may revise their rules if the changes are supported by a reasoned analysis, see *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 42 (1983). ''While the removal of a regulation may not entail the monetary expenditures and other costs of enacting a new standard, and accordingly, it may be easier for an agency to justify a deregulatory action, the direction in which an agency chooses to move does not alter the standard of judicial review established by law.'' Id. at 43.

The Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, such as the January 9, 2017, final rule regulating occupational exposure to beryllium:

> [t]he Secretary . . . shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

29 U.S.C. 665(b)(5). The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. See *Indus. Union Dept., AFL–CIO* v. *Am. Petroleum Inst.,* 448 U.S. 607, 641–42 (1980) (plurality opinion) (''*Benzene*''). OSHA need not make additional findings on risk for this proposal because OSHA previously determined that the beryllium standard addresses a significant risk, see 82 FR 2545–52, and the changes and clarifications proposed by this rulemaking do not affect that determination. See, *e.g., Pub. Citizen Health Research Grp.* v. *Tyson,* 796 F.2d 1479, 1502 n.16 (D.C. Cir. 1986) (rejecting the argument that OSHA must ''find that each and every aspect of its standard eliminates a significant risk'').

OSHA standards must also be both technologically and economically feasible. See *United Steelworkers* v. *Marshall,* 647 F.2d 1189, 1248 (D.C. Cir. 1980) (''*Lead I*''). The Supreme Court has defined feasibility as ''capable of being done.'' *Am. Textile Mfrs. Inst.* v. *Donovan,* 452 U.S. 490, 509–10 (1981) (''*Cotton Dust*''). The courts have further clarified that a standard is technologically feasible if OSHA proves a reasonable possibility, ''within the limits of the best available evidence, . . . that the typical firm will be able to develop and install engineering and work practice controls that can meet the [standard] in most of its operations.'' *Lead I,* 647 F.2d at 1272. With respect to economic feasibility, the courts have held that ''a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry.'' Id. at 1265 (internal quotation marks and citations omitted).

OSHA exercises significant discretion in carrying out its responsibilities under the Act. Indeed, ''[a] number of terms of the statute give OSHA almost unlimited discretion to devise means to achieve the congressionally mandated goal'' of ensuring worker safety and health. See *Lead I,* 647 F.2d at 1230 (citation omitted). Thus, where OSHA has chosen some measures to address a significant risk over other measures, those challenging the OSHA standard must ''identify evidence that their proposals would be feasible and generate more than a de minimis benefit to worker health.'' *N. Am.'s Bldg. Trades Unions* v. *OSHA,* 878 F.3d 271, 282 (D.C. Cir. 2017).

Although OSHA is required to set standards ''on the basis of the best available evidence,'' 29 U.S.C. 655(b)(5), its determinations are ''conclusive'' if supported by ''substantial evidence in the record considered as a whole,'' 29 U.S.C. 655(f). Similarly, as the Supreme Court noted in *Benzene,* OSHA must look to ''a body of reputable scientific thought'' in making determinations, but a reviewing court must ''give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge.'' *Benzene,* 448 U.S. at 656. When there is disputed scientific evidence in the record, OSHA must review the evidence on both sides and ''reasonably resolve'' the dispute. *Tyson,* 796 F.2d at 1500. The ''possibility of drawing two inconsistent conclusions from the evidence does not prevent the agency's finding from being supported by substantial evidence.'' *N. Am.'s Bldg. Trades Unions,* 878 F.3dat 291 (quoting *Cotton Dust,* 452 U.S. at 523) (alterations omitted). As the D.C. Circuit has noted, where ''OSHA has the expertise we lack and it has exercised that expertise by carefully reviewing the scientific data,'' a dispute within the scientific community is not occasion for the reviewing court to take sides about which view is correct. *Tyson,* 796 F.2d at 1500.

Finally, because section 6(b)(5) of the Act explicitly requires OSHA to set health standards that eliminate risk ''to the extent feasible,'' OSHA uses feasibility analysis rather than cost-benefit analysis to make standards-setting decisions dealing with toxic materials or harmful physical agents (29 U.S.C. 655(b)(5)). An OSHA standard in this area must be technologically and economically feasible—and also cost effective, which means that the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection—but OSHA cannot choose an alternative that provides a lower level of protection for workers' health simply because it is less costly. See *Int'l Union, UAW* v. *OSHA,* 37 F.3d 665, 668 (D.C. Cir. 1994); see also *Cotton Dust,* 452 U.S. at 514 n.32. In *Cotton Dust,* the Court explained:

> Congress itself defined the basic relationship between costs and benefits, by placing the ''benefit'' of worker health above all other considerations save those making attainment of this ''benefit'' unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in § 6(b)(5).

Cotton Dust, 452 U.S. at 509. Thus, while OSHA estimates the costs and benefits of its proposed and final rules, in part to ensure compliance with requirements such as those in Executive Orders 12866 and 13771, these calculations do not form the basis for the agency's regulatory decisions.

IV. Preliminary Economic Analysis and Regulatory Flexibility Act Certification (PEA)

Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)) require that OSHA estimate the benefits, costs, and net benefits of regulations, and analyze the impacts of certain rules that OSHA promulgates. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. For this proposal, possible effects of each provision on costs and benefits appear to be relatively small, and OSHA has not been able to quantify them. Nor has OSHA been able to quantify the cost savings it expects from preventing misinterpretation and misapplication of the standard. OSHA expects that this rule, if finalized, will increase understanding and increase compliance with the standard. This proposed rule is expected to be an E.O. 13771 deregulatory action. Moreover, and as mentioned above, OSHA expects this proposed rule would maintain safety and health protections for workers.

OSHA has preliminarily determined that the proposed rulemaking is not an ''economically significant regulatory action'' under Executive Order 12866 or a ''major rule'' under the Congressional Review Act (5 U.S.C. 801 *et seq.*), and its impacts do not trigger the analytical requirements of UMRA.

In promulgating the 2017 final rule, OSHA determined that the beryllium rule was both technologically and economically feasible. See 82 FR 2582–86, 2590–96, Summary of the Final Economic Analysis. The changes proposed herein are intended to align the rule more clearly with the intent of the 2017 final rule. Because OSHA has preliminarily determined that this proposal would decrease the costs of compliance by preventing misinterpretation and misapplication of the standard, OSHA has also preliminarily determined that the proposal is economically feasible.

OSHA invites public comment on all aspects of this PEA.

A. Proposed Clarifications

As previously explained in Section II, Discussion of Proposed Changes, many of the changes proposed in this NPRM are solely for purposes of clarification and therefore would not alter the requirements or scope of the beryllium standard, though they would facilitate its appropriate interpretation and application. These include: The addition of a definition of *beryllium sensitization* to paragraph (b); minor changes to the definitions of *CBD diagnostic center* and *chronic beryllium disease* in paragraph (b); minor changes to the written exposure control plan provisions in paragraph (f)(1)(i)(D) and paragraph (f)(2)(ii)(B); minor changes to provisions for the cleaning of PPE in paragraph (h)(3)(iii); minor changes to the cleaning of PPE upon entry to eating or drinking areas in paragraph (i)(4)(ii); a minor change in the PPE removal provision of paragraph (h)(2)(i); and minor changes to provisions for employee information and training in paragraphs (m)(4)(ii)(A) and

(m)(4)(ii)(E).[1] Because OSHA does not intend or expect these proposed changes to alter the requirements or the scope of the standard, OSHA does not anticipate that these changes would result in costs to employers, and anticipates they would trigger cost savings that follow from simplifying and facilitating compliance.

B. Proposed Revisions

Some proposed changes would go beyond clarification and alter certain requirements of the beryllium standard while maintaining safety and health protections for workers. The following subsections examine the provisions for which proposed changes may affect costs and the potential cost impact of these provisions, along with associated interrelated provisions. These provisions include: changes to the definitions of *beryllium work area, confirmed positive,* and *dermal contact with beryllium* in paragraph (b); a change to the requirements for washing facilities in paragraph (i)(1), a change to the requirements for provision of change rooms in paragraph (i)(2); changes to the requirements pertaining to disposal and recycling in paragraph (j)(3); a change to the requirements for medical surveillance following an employee's exposure to beryllium in an emergency in paragraph (k)(2); revision to provisions for evaluation at a CBD diagnostic center in paragraph (k)(7)(i); a change to the requirements for warning labels in paragraph (m)(3); and changes to the requirements for recordkeeping in paragraphs (n)(1)(ii)(F), (n)(3)(ii)(A), and (n)(4)(i). The agency preliminarily estimates that there would be no added costs due to the proposed changes to the definition of *dermal contact with beryllium,* the change rooms provision, the warning labels requirement, or the recordkeeping requirement, but that there would be potential cost savings from improving employer understanding and facilitating application of the rule. OSHA has preliminarily determined that cost savings would also result from the remainder of the changes, which would likewise improve employer understanding and are examined individually after this summary. OSHA has preliminarily identified only one new potential cost, which results from the proposed changes as a whole: a de minimis cost for the time employers will need to become familiar with any changes resulting from this rulemaking. OSHA therefore preliminarily anticipates that the net effect of the proposed changes would result in some cost savings.

1. Definition of Beryllium Work Area

The proposed definition of *beryllium work area* is any work area where materials that contain at least 0.1 percent beryllium by weight are processed either during any of the operations listed in proposed Appendix A; or where employees are, or can reasonably be expected to be, exposed to airborne beryllium at or above the action level. The proposed definition differs from the current definition in that, under the proposal, operations that are reasonably expected to release airborne beryllium only at concentrations below the action level and that do not appear in Appendix A would no longer trigger the establishment of a beryllium work area. In addition, the proposed definition would not trigger the establishment of a beryllium work area for operations where employees have the potential for dermal contact with beryllium, but that do not appear in Appendix A and are not reasonably expected to generate airborne beryllium at concentrations at or above the action level. Under the current definition, any potential for dermal contact results in a beryllium work area.

OSHA expects that the proposed definition of beryllium work area would not alter the number or location of beryllium work areas that employers in general industry must establish under the current rule. The proposed modification is not intended to significantly change the operations where a beryllium work area is established. Rather, it is intended to provide greater clarity to employers on when and where beryllium work areas are required and to avoid the potential for confusion—and potential expense inconsistent with the intended application of the rule—in the triggering of a beryllium work area at ''any level of exposure'' or on ''dermal contact with beryllium.'' The current standard's definition of beryllium work area requires, first, the presence of a process or operation that can release beryllium. As discussed in Section II, Discussion of Proposed Changes, OSHA has preliminarily determined that the operations listed in Appendix A of this proposal include common operations in general industry that can release beryllium, and the agency has requested comment on additional operations capable of releasing beryllium for inclusion in Appendix A.

In the FEA supporting the 2017 beryllium final rule, OSHA estimated that, on average, one beryllium work area would need to be established for every 12 at-risk workers in the exposure profile (2017 FEA, pp. V–164–165). The FEA defined an at-risk worker as one ''whose exposure to beryllium could result in disease or death'' and did not account for those workers who may have skin exposure but no airborne exposure to beryllium (2017 FEA, p. III–1). Because proposed Appendix A is designed to cover the same general industry processes as the current beryllium work area definition based on Chapter IV of the 2017 Beryllium FEA, and because those with dermal contact with beryllium but no airborne exposure were not accounted for in the 2017 cost estimate, OSHA anticipates the same number of beryllium work areas as estimated for the 2017 final rule. OSHA does, however, expect that this proposed clarification would result in reduced employer time for determining which areas should be demarcated as beryllium work areas under the standard. OSHA originally estimated that the initial set-up of a beryllium work area would take a supervisor four hours. OSHA expects that under the proposed revisions to the definition of a beryllium work area, employers will have more clarity about where beryllium work areas should be established and will spend less time identifying such areas. OSHA does not have sufficient information to quantify this time reduction but believes that, overall, this revision to the definition of a beryllium work area would produce a cost savings. OSHA requests comment on this preliminary determination, including comment on how to quantify the effect of greater clarity on the cost of setting up a beryllium work area. OSHA expects the proposed revisions would maintain safety and health protections for workers.

2. Definition of Confirmed Positive

OSHA is proposing to modify the definition of confirmed positive to require that the qualifying test results be obtained within one testing cycle (including the 30-day follow-up test period required after a first abnormal or borderline BeLPT test result), rather than over an unlimited time period that OSHA believes may lead to false positives that needlessly concern workers and their families and that do not enhance employee protections. The exact effect of this proposed change is uncertain as it is unknown how many employees would have a series of BeLPT results associated with a confirmed positive finding (two abnormal results, one abnormal and one borderline result, or three borderline

[1] See Section II, Discussion of Proposed Changes, for a detailed explanation of each proposed change to the standard.

results) over an unlimited period of time, but would not have any such combination of results within a single testing cycle. OSHA preliminarily concludes that this change would not increase compliance costs and would incidentally yield some cost savings by lessening the likelihood of false positives. OSHA invites comment on this preliminary conclusion. Again, OSHA expects the proposed change would maintain safety and health protections for workers.

3. Definition of Dermal Contact With Beryllium

OSHA is proposing to modify the definition for *dermal contact with beryllium,* but does not anticipate any cost impact from this change other than possible prevention of expenses that misinterpretation or misapplication of the standard might lead to. Paragraph (b) of the beryllium standard currently defines *dermal contact with beryllium* as skin exposure to soluble beryllium compounds, beryllium solutions, or dust, fumes, or mists containing beryllium, where these materials contain beryllium in concentrations greater than or equal to 0.1 percent by weight. OSHA is proposing two changes to this definition. First, OSHA proposes to add the term ''visible'' to the definition, so that the third form of dermal contact with beryllium would be limited to contact with ''visible dust, fumes, or mists'' containing beryllium in concentrations greater than or equal to 0.1 percent by weight. Second, OSHA proposes to add a sentence to the definition specifying that handling of beryllium materials in a non-particulate solid form that is free from visible dust containing beryllium in concentrations greater than or equal to 0.1 percent by weight is not considered dermal contact under the standard.

The 2017 FEA estimated the costs of provisions related to dermal contact with beryllium based on the number of employees working in application groups where beryllium is processed. Following the publication of the 2017 standard, OSHA received feedback from employers concerned that if the definition was not limited to ''visible'' dust, fumes, or mist, then all employees in a facility must be considered to have dermal contact with beryllium because they may have come into contact with non-visible beryllium particulate outside of a beryllium work area or when handling beryllium materials in non-particulate solid form. This was not OSHA's intent, as reflected in OSHA's previous cost estimates for the relevant beryllium work area and PPE provisions. One employer also expressed concern that handling solid beryllium would fall within the definition of dermal contact with beryllium, but again that was not OSHA's intent, and OSHA had not estimated costs arising from protection from contact with this form of beryllium. As OSHA explained in the 2017 final rule, beryllium-containing solid objects, or ''articles,'' with uncompromised physical integrity, are unlikely to release beryllium that would pose a health hazard for workers (82 FR at 2640). The cost of compliance with provisions triggered by dermal contact with beryllium is therefore not expected to increase as a result of either change to this definition.[2] OSHA furthermore anticipates its proposed revisions would maintain safety and health protections for workers.

4. Hygiene Areas and Practices

OSHA is proposing two changes to the hygiene areas and practices provision to account for the proposed changes to the definition of a beryllium work area and to ensure that the hygiene provisions related to washing facilities and change rooms will still apply to employees who can reasonably be expected to have dermal contact with beryllium regardless of whether they work in beryllium work areas as defined in the revised definition. First, OSHA is proposing a change in the wording of paragraph (i)(1), which specifies the employees for whom employers must provide washing facilities. As currently written, paragraph (i)(1) applies to each employee working in a beryllium work area. OSHA is proposing to apply the requirements of paragraph (i)(1) to each employee who can reasonably be expected to have dermal contact with beryllium, in addition to each employee working in a beryllium work area, to account for the proposed removal of dermal contact with beryllium as a trigger for establishing a beryllium work area. Second, OSHA is proposing a change in the wording of paragraph (i)(2) (change rooms). As currently written, paragraph (i)(2) applies to employees who work in a beryllium work area. OSHA is proposing to apply the requirements of paragraph (i)(2) to employees who are required to use personal protective clothing or equipment under paragraph (h)(1)(ii) of the beryllium standard, instead of to employees who work in a beryllium work area.

As discussed in Section B.1 of this PEA, OSHA is proposing several changes to the definition of beryllium work area to clarify where a beryllium work area should be established. One of the changes proposed is to remove dermal contact with beryllium as one of the triggers that would require an employer to establish a beryllium work area. If this proposed change to the definition of beryllium work area is finalized, it is OSHA's intention that the hygiene provisions related to washing facilities and change rooms will still apply to employees who can reasonably be expected to have dermal contact with beryllium regardless of whether they work in beryllium work areas as defined in the revised definition. OSHA therefore expects that the proposed change to the definition of *dermal contact with beryllium,* discussed in Section B.3, will not increase or decrease the number of change rooms or washing facilities from estimates of the 2017 FEA for these provisions, and thus will have no impact on compliance costs beyond what was originally contemplated in the 2017 final rule. Likewise, OSHA expects the proposed changes would maintain safety and health protections for workers.

5. Disposal, Recycling, and Reuse

Paragraph (j)(3) addresses disposal and recycling of materials that contain beryllium in concentrations of 0.1 percent by weight or more or that are contaminated with beryllium. That paragraph currently specifies that (1) materials designated for disposal must be disposed of in sealed, impermeable enclosures, such as bags or containers, that are labeled according to paragraph (m)(3) of the beryllium standard, and (2) materials designated for recycling must be cleaned to be as free as practicable of surface beryllium contamination and labeled according to paragraph (m)(3), or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled according to paragraph (m)(3). OSHA is proposing several changes to this paragraph, changes that do not increase the costs of complying with the standard and may also result in savings to employers by preventing misinterpretation or misapplication of the rule.

First, OSHA is proposing that provisions pertaining to recycling and disposal also address reuse, in addition to disposal and recycling, because in some cases materials may be directly reused without being recycled. This is to ensure that workers exposed to materials designated for reuse are adequately protected from dermal exposure to materials containing or

[2] If there were a change in the cost of compliance with provisions triggered on dermal contact with beryllium, it would be a cost savings because these proposed changes clarify that the definition is not intended to be as broad as some may have believed it to be.

contaminated with more than a trace amount of beryllium. In the 2017 FEA, the costs attributed to the provisions of paragraph (j)(3) for recycling included both direct reuse of materials as well as recycling (82 FR at 2695). Thus, this proposed change to paragraph (j)(3) would not change the costs of compliance with the standard.

Second, proposed paragraph (j)(3)(i) would clarify that labeling requirements under paragraph (m)(3) apply when the employer transfers materials to another party for disposal, recycling, or reuse. This is not a substantive change to the standard, but rather a reorganization of the existing provisions, and therefore does not impact costs of compliance with the standard.

Third, the proposed addition of the phrase ''except for intra-plant transfers'' to paragraphs (j)(3)(ii) and (iii) clarifies that the requirements in paragraph (j)(3) do not apply to transfers within a plant, and also would not be a substantive change to the standard. Since this proposed change would not alter the requirements of the standard, it would not affect the costs of compliance with the standard.

Fourth, proposed paragraphs (j)(3)(ii) and (iii) would require that materials not otherwise cleaned be placed in enclosures that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport. This proposed change would clarify the final standard's requirement that the materials be placed in ''sealed, impermeable enclosures.'' As discussed in the preamble to the final standard (82 FR 2470, 2695), OSHA intended this requirement to be broad and the provision performance-oriented, so as to allow employers in a variety of industries flexibility to decide what type of enclosures (*e.g.,* bags or other containers) are best suited to their workplace and the nature of the beryllium-containing materials they are disposing or designating for reuse outside the facility. The term ''impermeable'' was not intended to mean absolutely impervious to rupture; rather, OSHA explained that the enclosures should be impermeable to the extent that they would not allow materials to escape ''under normal conditions of use'' (82 FR 2695). Thus, the proposed change merely makes explicit what had been intended in the 2017 final rule, and would not increase or decrease the costs of compliance with the standard beyond saving expense that could follow from its misinterpretation or misapplication.

Fifth, paragraph (j)(3)(iii) would also clarify the cleaning requirements of the beryllium standard by removing the requirement that contaminated areas be cleaned ''of surface beryllium contamination.'' Elsewhere in the standard, OSHA uses the phrase ''as free as practicable of beryllium,'' and OSHA proposes to use that phrase in place of ''of surface beryllium contamination.'' OSHA has discussed the meaning of the phrase ''as free as practicable'' in the summary and explanation of paragraph (j) in the 2017 final rule (82 FR 2690), as well as previously in a 2014 letter of interpretation explaining the phrase in the context of the agency's standard for hexavalent chromium.[3] OSHA believes the phrase ''as free as practicable of beryllium'' will more clearly convey the cleaning requirements under the beryllium standard than requiring cleaning ''of surface beryllium contamination.'' The proposed change would not substantively alter any of the employers' cleaning process costed in the 2017 FEA, and therefore would not increase or decrease the costs of compliance with the standard beyond saving expense that could follow from misunderstanding.

Finally, proposed paragraph (j)(3)(ii) would incorporate a new option for cleaning materials designated for disposal, using the same ''as free as practicable of beryllium'' language used in the recycling and reuse provisions in proposed (j)(3)(iii). The beryllium standard currently does not include an option of cleaning materials designated for disposal and instead requires enclosure of all materials in containers. The agency had not previously considered situations where it would be impractical to require enclosure because the materials in question were large items such as machines or structures that may contain, or be contaminated with, beryllium, rather than more common items, such as beryllium scrap metal or shavings. It is OSHA's understanding that these larger items need not be enclosed when they are cleaned in accordance with the existing housekeeping provisions, which also require employers to keep their work areas as free as practicable of beryllium. Regardless of whether an employer chooses to clean or enclose materials designated for disposal, the labeling requirements under proposed paragraph (j)(3)(i) would still apply and would require the materials designated for disposal to be labeled in accordance with paragraph (m)(3) of this standard. This proposed change would merely allow another option for materials designated for disposal. Because it would impose no additional requirements beyond the existing housekeeping duties already necessary before larger beryllium-contaminated items could be moved away from beryllium work areas, there is no additional cost. OSHA expects employers to choose the lowest-cost option, so there may be cost savings in some individual cases as compared to the cost of enclosing. However, OSHA does not know how many employers may choose this option and therefore does not have sufficient information to quantify this potential cost savings at this time.[4] OSHA expects the proposed changes would maintain safety and health protections for workers.

6. Medical Surveillance Provisions

Under paragraph (k)(2)(i)(B), the employer must provide a medical examination including a BeLPT within 30 days after determining that the employee shows signs or symptoms of CBD or other beryllium-related health effects or the employee is exposed to beryllium in an emergency. The standard provides that these employees must also be offered a BeLPT every two years following their initial BeLPT unless they are confirmed positive (paragraph (k)(3)(ii)(E)).

OSHA proposes to remove the requirement for a medical examination within 30 days of determining that an employee has been exposed in an emergency and add paragraph (k)(2)(iv), which would require the employer to offer a medical examination at least one year after, but no more than two years after, the employee is exposed to beryllium in an emergency. As discussed in the Discussion of Proposed Changes, testing within the first 30 days may be premature because beryllium sensitization might not be detected within 30 days after exposure in all individuals who may become sensitized. OSHA believes that the proposed time period for providing a medical examination would be more likely to enable detection of sensitization in more employees in the first test following exposure in an emergency, providing better worker protection.

[3] OSHA, Nov. 5, 2014, Letter of Interpretation, available at *https://www.osha.gov/laws-regs/standardinterpretations/2014-11-05.*

[4] The 2017 FEA did not estimate a cost for enclosures for materials designated for disposal because OSHA judged that beryllium materials not used in a final product would typically either be large enough to provide sufficient economic incentive for recycling, or small enough that they could be vacuumed up (FEA, p. V–188). Therefore, in addition to having no basis to quantify how many employers may choose cleaning over containers, OSHA does not have a basis for estimating the amount of any potential cost savings for such employers.

In the agency's FEA for the January 2017 final rule, the agency estimated that a very small number of employees would be affected by emergencies in a given year, likely less than 0.1 percent of the affected population, representing a small addition to the costs of medical surveillance for the standard (FEA, p. V–196). Under the current rule, some employees may require two examinations to be confirmed positive: An initial test within the initial 30-day period and (assuming the first test is normal) a second BeLPT at least two years later. Under the proposed rule, OSHA expects more of the employees who become sensitized from exposure in an emergency to be confirmed positive through a single test cycle because that test will be administered one to two years following the emergency. The general result is the elimination of one cycle of testing that appears to be premature, ensuring better detection for more employees and incidentally triggering some cost savings.[5]

To the extent that lengthening the time period in which the test must be offered from within 30 days to between one and two years leads to earlier confirmed positive results (within two years, as opposed to within two years plus 30 days), the proposed change would slightly accelerate costs to the employer for earlier CBD diagnostic center referral and medical removal protection. OSHA estimates that this proposed change would affect a very small percentage of an already very small population. And this proposed revision would only potentially change the timing of the already-required BeLPT, CBD diagnostic center referral, and medical removal protection.

The end result from a cost perspective is that the cost savings from the potential avoidance of a premature BeLPT within 30 days following an emergency is likely to be largely canceled out by the acceleration of the cost of the CBD diagnostic center evaluation and medical removal protection. OSHA has preliminarily determined that the net cost impact would be slight, with some possible cost savings.

Paragraph (k)(7)(i) requires that the employer provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employee and employer within 30 days of the employer receiving a medical opinion or written medical report that recommends referral to a CBD diagnostic center, or a written medical report indicating that the employee has been confirmed positive or diagnosed with CBD. OSHA is proposing a change to paragraph (k)(7)(i) to account for the proposed revision to the definition of *CBD diagnostic center* discussed earlier in this proposal. As explained in Section II, Discussion of Proposed Changes, OSHA is proposing to amend this definition to clarify that a CBD diagnostic center must be capable of performing a variety of tests commonly used in the diagnosis of CBD, but need not necessarily perform all of the tests during all CBD evaluations. Nonetheless, OSHA intends that the employer provide those tests if deemed appropriate by the examining physician at the CBD diagnostic center. Accordingly, OSHA is proposing to amend paragraph (k)(7)(i) to clarify that the employer must provide, at no cost to the employee and within a reasonable time after consultation with the CBD diagnostic center, any of the following tests that a CBD diagnostic center must be capable of performing, if deemed appropriate by the examining physician at the CBD diagnostic center: a pulmonary function test as outlined by American Thoracic Society criteria testing, bronchoalveolar lavage (BAL), and transbronchial biopsy. This proposed change to paragraph (k)(7) would not change the requirements of the beryllium standard and therefore would not change the costs of compliance with the standard.

OSHA is also proposing that the employer provide an initial consultation with the CBD diagnostic center, rather than the full evaluation, within 30 days of the employer receiving one of the types of documentation listed in paragraph (k)(7)(i)(A) or (B). As explained in Section II, Discussion of Proposed Changes, this consultation would allow the employee to speak with a physician to discuss concerns and ask questions prior to a medical evaluation for CBD, and would allow the physician to explain the types of tests that are recommended based on the employee's medical findings.

The proposed provision could result in cost savings. This initial consultation can be done in conjunction with the tests but it is not required to be. As the initial consultation may be conducted remotely, by phone or virtual conferencing, the cost of the consultation would consist only of time spent by the employee and the physician and would not have to include any travel or accommodation. This proposed change would not prohibit the employer from providing both the consultation and the full evaluation at the same appointment, as long as the appointment is within 30 days of the employer receiving one of the types of documentation listed in paragraph (k)(7)(i)(A) or (B). In the 2017 FEA, OSHA accounted for the cost of both the employee's time and a physician's time for a 15-minute discussion (2017 FEA, p. V–206). Because the consultation would replace this initial discussion, there would be no additional cost. Furthermore, OSHA expects that allowing more flexibility in scheduling the tests at the CBD diagnostic center would allow employers to find more economical travel and accommodation options. To the extent that it takes longer than 30 days to schedule the tests at the CBD diagnostic center, employers may realize a cost savings due to retaining funds during the delay. OSHA cannot quantify the effect of this flexibility on any cost savings at this time, but travel and accommodation costs related to the CBD diagnostic center evaluation are only six percent of total CBD diagnostic center referral costs. The agency therefore preliminarily concludes these changes would produce minor, if any, cost savings. OSHA invites comment on this preliminary assessment.

OSHA also notes that the proposed changes described here would maintain safety and health protections for workers.

7. Labeling

Paragraph (m)(3) addresses warning label requirements. This paragraph requires the employer to label each bag and container of clothing, equipment, and materials contaminated with beryllium, and specifies precise wording on the label. OSHA is proposing to modify the language in paragraph (m)(3) to remove the words ''bag and'' and insert the descriptive adjective ''immediate'' to clarify that the employer need only label the immediate container of beryllium-contaminated items. The proposed clarification would be consistent with the hazard communication standard (HCS (§ 1910.1200) regarding bags or containers within larger containers. Under the HCS, only the primary or immediate container must be labeled

[5] Employees already participating in a medical surveillance program are entitled to a BeLPT screening every two years, even absent an emergency, but the initial 30-day screening following an emergency, required under the existing rule, would also satisfy the requirement for the medical surveillance two-year screening. Assuming that this initial analysis does not result in a confirmed positive diagnosis, that employee would not be confirmed positive until a second test two years later under the current rule. Under the proposal, the second test could be forgone and detection could occur sooner than it would under the current rule.

and not the larger container holding the labeled bag or container.

In the 2017 Beryllium FEA, costs were taken only for the bag label and not for the label of any larger container holding the bag. Thus, this proposed clarification has no cost implications. And the revision would maintain safety and health protections for workers.

8. Recordkeeping

OSHA is proposing to modify paragraph (n), Recordkeeping, by removing the requirement to include each employee's Social Security number (SSN) in the air monitoring data ((n)(1)(ii)(F)), medical surveillance ((n)(3)((ii)(A)), and training ((n)(4)(i)) provisions. This proposed change would not require employers to delete employee SSNs from existing records, or to include an alternative unique employee identifier on those records. Furthermore, it would not mandate a specific type of identification method that employers should use on newly-created records, but would instead provide employers with the flexibility to develop systems that best work for their unique situations. As a result, OSHA estimates that this proposed revision has no cost implications—and it would maintain safety and health protections for workers.

C. Additional Familiarization

OSHA expects that if this proposal is finalized, employers will spend a small amount of time reviewing these proposed changes. This amount of time would be negligible compared to the amount of time employers spent reviewing the 2017 final beryllium rule. In addition, OSHA notes that many affected employers would already be familiar with the proposed changes because the proposed regulatory text changes were made public in April 2018 (Document ID OSHA–H005C–2006–0870–2156). OSHA therefore expects the cost of familiarization with this proposal would be de minimis and welcomes comment on this preliminary determination.

D. Economic and Technological Feasibility

In the FEA in support of OSHA's 2017 Beryllium Final Rule, OSHA concluded that the general industry beryllium standard was economically and technologically feasible (82 FR 2471). As explained above, OSHA anticipates that none of the changes in this proposal would impose any new employer obligations or increase the overall cost of compliance, while some of the changes in this proposal would clarify and simplify compliance in such a way that results in cost savings. OSHA expects that the cost of any time spent reviewing the changes in this proposal, as described above in Section C, will be more than offset by cost savings. None of the revisions to the standard requires any new controls or other technology. OSHA has therefore preliminarily determined that this proposal is also economically and technologically feasible.

E. Effects on Benefits

In the 2017 FEA, OSHA attributed approximately 67 percent of the beryllium sensitization cases and the CBD cases avoided, and none of the lung cancer cases avoided, solely to the ancillary provisions of the standard. (2017 FEA, Document ID OSHA–H005C–2006–0870–2042, p. VII–4–VII–5, VII–24.) This estimate was based on the ancillary provisions as a whole, rather than each provision separately.

As described in Section II, Discussion of Proposed Changes, the proposed changes are intended to clarify and simplify compliance with certain ancillary provisions of the 2017 general industry beryllium standard and facilitate employer understanding of its requirements. This NPRM does not propose to remove any ancillary provision. Thus, the group of ancillary provisions that would result from finalizing these proposed revisions to the beryllium standard includes a provision similar to each of those in the 2017 final rule.

Furthermore, the agency considered the potential effect of each proposed change to ancillary provisions on employee protections. OSHA believes that the proposed changes would maintain safety and health protections for workers while aligning the standard with the intent behind the 2017 final rule and otherwise preventing costs that could follow from misinterpretation or misapplication of the standard. Moreover, facilitating employer understanding and compliance has the benefit of enhancing worker protections overall. Because the proposed revisions to the standard would not remove or change the general nature of any ancillary provisions, and because the agency expects proposed revisions to maintain safety and health protections for workers and facilitate employer understanding and compliance, OSHA preliminarily determines that the effect of these proposed changes on benefits of the standard as a whole would be to increase them by enhancing worker protections overall and by preventing costs that follow from misunderstanding the standard.

F. Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (as amended), OSHA has examined the regulatory requirements of this proposal to revise the general industry beryllium standard to determine whether they would have a significant economic impact on a substantial number of small entities. The proposal would modify the general industry standard to clarify certain provisions and simplify or improve compliance. It would not impose any new duties or increase the overall cost of compliance and would provide some cost savings. OSHA therefore expects that this proposal would not have a significant economic impact on any small entities. Accordingly, OSHA certifies that this proposal would not have a significant economic impact on a substantial number of small entities.

V. OMB Review Under the Paperwork Reduction Act of 1995

A. Overview

The standard for occupational exposure to beryllium in general industry (29 CFR 1910.1024) contains information collection requirements that are subject to the Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations at 5 CFR part 1320. The agency is proposing to revise the existing previously approved paperwork package under OMB control number 1218–0267 for general industry. This proposal would remove provisions in the beryllium standard for general industry that require employers to collect and record employees' social security numbers; modify the housekeeping requirements that require employers to label those materials designated for disposal, recycling, or reuse that either contain at least 0.1% beryllium by weight or are contaminated with beryllium; and clarify what tests are required when an employee is referred to a CBD diagnostic center.

The PRA defines a *collection of information* as ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format.'' (44 U.S.C. 3502(3)(A)). Under the PRA, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it, and the agency displays a currently valid OMB control number (44 U.S.C. 3507). Also, notwithstanding any other provision of

law, no employer shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

B. Solicitation of Comments

OSHA prepared and submitted an Information Collection Request (ICR) to OMB proposing to remove the current collection of information that requires employers to collect and record social security numbers from the existing OMB approved paperwork package in accordance with 44 U.S.C. 3507(d). The ICR also reflects proposed changes to the beryllium standard's housekeeping and medical surveillance provisions, described below. The agency solicits comments on these proposed changes to the collection of information requirements and reduction in estimated burden hours associated with these requirements, including comments on the following items:

- Whether the proposed collections of information are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the collections of information, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the compliance burden on employers, for example, by using automated or other technological techniques for collecting and transmitting information.

C. Proposed Information Collection Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(2), the following paragraphs provide information about this ICR.

1. *Title:* The Occupational Exposure to Beryllium Standard for General Industry

2. *Description of the ICR:* The proposal would remove the collection and recording of social security numbers in general industry and modify housekeeping and CBD diagnostic center requirements for the beryllium in general industry ICR.

3. *Brief Summary of the Information Collection Requirements:* The proposed beryllium ICR would remove and revise the collection of information requirements contained in the beryllium general industry standard by modifying and clarifying the intent for certain collection of information requirements. The proposed changes to the beryllium general industry standard would remove the collection and recording of Social Security Numbers from air monitoring, medical surveillance, and training provisions under paragraph (n) of the standard.

In addition, OSHA is proposing to update paragraph (j)(3) by clarifying the labeling requirements for beryllium-contaminated materials designated for disposal, recycling, or reuse. The proposed change will also clarify how materials designated for recycling or reuse that either contain at least 0.1% beryllium by weight or are contaminated with beryllium must be cleaned to be as free as practicable of beryllium or placed in enclosures that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport, such as bags or containers.

OSHA is also proposing to revise both the definition of a CBD diagnostic center and paragraph (k)(7)(i) to indicate that the evaluation at the CBD diagnostic center must include a pulmonary function test as outlined by American Thoracic Society criteria, bronchoalveolar lavage (BAL), and transbronchial biopsy, only if deemed appropriate by an examining physician. These proposed changes clarify the original intent of these requirements. The agency believes that these changes would have benefits to both employees and employers and overall cost savings, but OSHA has not quantified those benefits and savings for this analysis. These proposed changes to the information collection requirements in this information collection request would affect the existing ICR but would have no measureable impact on employer burden, and would therefore impose no additional burden hours or costs for the employer.

Totals estimated for burden hours and cost:

4. *OMB Control Numbers:* 1218–0267.

5. *Affected Public: Business or other for-profit.* This standard applies to employers in general industry who have employees that may have occupational exposures to any form of beryllium, including compounds and mixtures, except those articles and materials exempted by paragraphs (a)(2) and (a)(3).

6. *Number of Respondents:* [5,872].

7. *Frequency of responses:* On occasion; quarterly, semi-annually, annually; biannually.

8. *Number of responses:* [141,749].

9. *Estimated Total Burden Hours:* 83,694.

10. *Estimated Cost:* [$20,585,273].

D. Submitting Comments

Members of the public who wish to comment on the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (RIN–1218–AD20), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.* The agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket Number OSHA–2018–0003), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**. Comments submitted in response to this notice are public records; therefore, OSHA cautions commenters about submitting personal information such as Social Security Numbers and dates of birth.

E. Docket and Inquiries

To access the docket to read or download comments and other materials related to this paperwork determination, including the complete ICR (containing the Supporting Statement with attachments describing the paperwork determinations in detail), use the procedures described under the section of this notice titled **ADDRESSES**. You also may obtain an electronic copy of the complete ICR by visiting the web page at *http://www.reginfo.gov/public/do/PRAMain.* Scroll under ''Currently Under Review'' to ''Department of Labor (DOL)'' to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Seleda Perryman, Directorate of Standards and Guidance, telephone (202) 693–2222.

VI. Federalism

OSHA reviewed this proposal in accordance with the Executive Order on Federalism (E.O. 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when clear constitutional and statutory authority exists and the problem is national in scope. E.O. 13132 provides for preemption of State law

only with the expressed consent of Congress. Any such preemption is to be limited to the extent possible.

Under Section 18 of the OSH Act, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as ''State Plan States'' (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards. Subject to these requirements, State Plan States are free to develop and enforce under State law their own requirements for safety and health standards.

OSHA previously concluded that promulgation of the beryllium standard complies with E.O. 13132 (82 FR at 2633), so this proposal complies with E.O. 13132. In States without OSHA-approved State Plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, this proposal would limit State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA-approved State Plans, this rulemaking would not significantly limit State policy options.

VII. State Plan States

When Federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 28 States and U.S. Territories with their own OSHA approved occupational safety and health plans (''State Plan States'') must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.,* because an existing State standard covering this area is ''at least as effective'' as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule. State Plans must adopt the Federal standard or complete their own standard within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States are not required to amend their standards, although the agency may encourage them to do so. The 28 States and U.S. territories with OSHA-approved occupational safety and health plans are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to State and local government employees only.

This proposal is clarifying and simplifying in nature and would impose no new requirements. Therefore, no new State standards would be required beyond those already required by the promulgation of the January 2017 beryllium standard for general industry. State-Plan States may nonetheless choose to conform to these proposed revisions.

VIII. Unfunded Mandates Reform Act

OSHA reviewed this proposal according to the Unfunded Mandates Reform Act of 1995 (''UMRA''; 2 U.S.C. 1501 *et seq.*) and Executive Order 12875 (58 FR 58093). As discussed above in Section IV (''Preliminary Economic Analysis and Regulatory Flexibility Certification'') of this preamble, the agency preliminarily determined that this proposal would not impose significant additional costs on any private- or public-sector entity. Further, OSHA previously concluded that the rule would not impose a Federal mandate on the private sector in excess of $100 million (adjusted annually for inflation) in expenditures in any one year (82 FR at 2634). Accordingly, this proposal would not require significant additional expenditures by either public or private employers.

As noted above under Section VII (''State-Plan States''), the agency's standards do not apply to State and local governments except in States that have elected voluntarily to adopt a State Plan approved by the agency. Consequently, this proposal does not meet the definition of a ''Federal intergovernmental mandate'' (see Section 421(5) of the UMRA (2 U.S.C. 658(5))). Therefore, for the purposes of the UMRA, the agency certifies that this proposal would not mandate that State, local, or Tribal governments adopt new, unfunded regulatory obligations of, or increase expenditures by the private sector by, more than $100 million in any year.

IX. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this proposed rule in accordance with E.O. 13175 (65 FR 67249) and determined that it does not have ''tribal implications'' as defined in that order. This proposal does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

X. Environmental Impacts

OSHA has reviewed this proposed beryllium rule according to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). OSHA has made a preliminary determination that this proposed rule would have no significant impact on air, water, or soil quality; plant or animal life; the use of land; or aspects of the external environment.

XI. Authority

Signed at Washington, DC, on November 30, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

List of Subjects in 29 CFR Part 1910

Beryllium, General industry, Health, Occupational safety and health.

Amendments to Standards

For the reasons stated in the preamble of this notice of proposed rulemaking, OSHA is amending 29 CFR part 1910 to read as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS [AMENDED]

■ 1. The authority section for subpart Z of 29 CFR part 1910 continues to read as follows:

Authority: 29 U.S.C. 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), or 1–2012 (77 FR 3912); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

Section 1910.1030 also issued under Pub. L. 106–430, 114 Stat. 1901.

Section 1910.1201 also issued under 49 U.S.C. 5101 *et seq.*

■ 2. Amend § 1910.1024 as follows:
■ a. Add a definition for ''Beryllium sensitization'' in paragraph (b);
■ b. Revise in alphabetical order the definitions of ''Beryllium work area,'' ''CBD diagnostic center,'' ''Chronic beryllium disease (CBD),'' ''Confirmed positive,'' and ''Dermal contact with beryllium'' in paragraph (b);
■ c. Revise paragraphs (f)(1)(i)(D) and (ii)(B);

■ d. Revise paragraphs (h)(2)(i) and (3)(iii);
■ e. Revise paragraphs (i)(1), (2), and (4)(ii);
■ f. Revise paragraph (j)(3);
■ g. Revise paragraphs (k)(2)(i)(B), (iv), and (7)(i);
■ h. Revise paragraphs (m)(3), (4)(ii)(A), and (E);
■ i. Revise paragraphs (n)(1)(ii)(F), (3)(ii)(A), and (4)(i); and
■ j. Revise paragraph (p).

The revisions and additions read as follows:

§ 1910.1024 Beryllium.

* * * * *

(b) * * *

Beryllium sensitization means a response in the immune system of a specific individual who has been exposed to beryllium. There are no associated physical or clinical symptoms and no illness or disability with beryllium sensitization alone, but the response that occurs through beryllium sensitization can enable the immune system to recognize and react to beryllium. While not every beryllium-sensitized person will develop chronic beryllium disease (CBD), beryllium sensitization is essential for development of CBD.

Beryllium work area means any work area where materials that contain at least 0.1 percent beryllium by weight are processed either: (1) During any of the operations listed in Appendix A of this Standard; or (2) where employees are, or can reasonably be expected to be, exposed to airborne beryllium at or above the action level.

CBD diagnostic center means a medical diagnostic center that has a pulmonologist or pulmonary specialist on staff and on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD). The CBD diagnostic center must have the capacity to perform pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The CBD diagnostic center must also have the capacity to transfer BAL samples to a laboratory for appropriate diagnostic testing within 24 hours. The pulmonologist or pulmonary specialist must be able to interpret the biopsy pathology and the BAL diagnostic test results.

Chronic beryllium disease (CBD) means a chronic granulomatous lung disease caused by inhalation of airborne beryllium by an individual who is beryllium-sensitized.

Confirmed positive means the person tested has had two abnormal BeLPT test results, an abnormal and a borderline test result, or three borderline test results obtained within the 30 day follow-up test period required after a first abnormal or borderline BeLPT test result. It also means the result of a more reliable and accurate test indicating a person has been identified as having beryllium sensitization.

* * * * *

Dermal contact with beryllium means skin exposure to: (1) Soluble beryllium compounds containing beryllium in concentrations greater than or equal to 0.1 percent by weight; (2) solutions containing beryllium in concentrations greater than or equal to 0.1 percent by weight; or (3) visible dust, fumes, or mists containing beryllium in concentrations greater than or equal to 0.1 percent by weight. The handling of beryllium materials in non-particulate solid form that are free from visible dust containing beryllium in concentrations greater than or equal to 0.1 percent by weight is not considered dermal contact under the standard.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(D) Procedures for minimizing cross-contamination, including the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas;

* * * * *

(ii) * * *

(B) The employer is notified that an employee is eligible for medical removal in accordance with paragraph (l)(1) of this standard, referred for evaluation at a CBD diagnostic center, or shows signs or symptoms associated with exposure to beryllium; or

* * * * *

(h) * * *

(2) * * *

(i) The employer must ensure that each employee removes all beryllium-contaminated personal protective clothing and equipment at the end of the work shift, at the completion of all tasks involving beryllium, or when personal protective clothing or equipment becomes visibly contaminated with beryllium, whichever comes first.

* * * * *

(3) * * *

(iii) The employer must inform in writing the persons or the business entities who launder, clean or repair the personal protective clothing or equipment required by this standard of the potentially harmful effects of exposure to beryllium and that the personal protective clothing and equipment must be handled in accordance with this standard.

(i) * * *

(1) General. For each employee working in a beryllium work area or who can reasonably be expected to have dermal contact with beryllium, the employer must:

* * * * *

(2) Change rooms. In addition to the requirements of paragraph (i)(1)(i) of this standard, the employer must provide employees who are required to use personal protective clothing or equipment under paragraph (h)(1)(ii) of this standard with a designated change room in accordance with this standard and the Sanitation standard (§ 1910.141) where employees are required to remove their personal clothing.

* * * * *

(4) * * *

(ii) No employees enter any eating or drinking area with beryllium-contaminated personal protective clothing or equipment unless, prior to entry, it is cleaned, as necessary, to be as free as practicable of beryllium by methods that do not disperse beryllium into the air or onto an employee's body; and

* * * * *

(j) * * *

(3) *Disposal, recycling, and reuse.*

(i) When the employer transfers materials that contain at least 0.1% beryllium by weight or are contaminated with beryllium to another party for disposal, recycling, or reuse, the employer must label the materials in accordance with paragraph (m)(3) of this standard;

(ii) Except for intra-plant transfers, materials designated for disposal that contain at least 0.1% beryllium by weight or are contaminated with beryllium must be cleaned to be as free as practicable of beryllium or placed in enclosures that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport, such as bags or containers; and

(iii) Except for intra-plant transfers, materials designated for recycling or reuse that contain at least 0.1% beryllium by weight or are contaminated with beryllium must be cleaned to be as free as practicable of beryllium or placed in enclosures that prevent the release of beryllium-containing particulate or solutions under normal conditions of use, storage, or transport, such as bags or containers.

* * * * *

(k) * * *

(2) * * *

(i) * * *

(B) An employee meets the criteria of paragraph (k)(1)(i)(B).

* * * * *

(iv) At least one year but no more than two years after an employee meets the criteria of paragraph (k)(1)(i)(C).

* * * * *

(7) * * *

(i) The employer must provide an evaluation at no cost to the employee at a CBD diagnostic center that is mutually agreed upon by the employer and the employee. The employer must also provide, at no cost to the employee and within a reasonable time after the initial consultation with the CBD diagnostic center, any of the following tests if deemed appropriate by the examining physician at the CBD diagnostic center: Pulmonary function testing (as outlined by the American Thoracic Society criteria), bronchoalveolar lavage (BAL), and transbronchial biopsy. The initial consultation with the CBD diagnostic center must be provided within 30 days of:

* * * * *

(m) * * *

(3) Warning labels. Consistent with the HCS (§ 1910.1200), the employer must label each immediate container of clothing, equipment, and materials contaminated with beryllium, and must, at a minimum, include the following on the label:

DANGER
CONTAINS BERYLLIUM
MAY CAUSE CANCER
CAUSES DAMAGE TO LUNGS
AVOID CREATING DUST
DO NOT GET ON SKIN

(4) * * *

(ii) * * *

(A) The health hazards associated with airborne exposure to and dermal contact with beryllium, including the signs and symptoms of CBD;

* * * * *

(E) Measures employees can take to protect themselves from airborne exposure to and dermal contact with beryllium, including personal hygiene practices;

* * * * *

(n) * * *

(1) * * *

(ii) * * *

(F) The name and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

* * * * *

(3) * * *

(ii) * * *

(A) Name and job classification;

* * * * *

(4) * * *

(i) At the completion of any training required by this standard, the employer must prepare a record that indicates the name and job classification of each employee trained, the date the training was completed, and the topic of the training.

* * * * *

(p) Appendix. Appendix A to § 1910.1024—Operations for Establishing Beryllium Work Areas

Paragraph (b) of this standard defines a beryllium work area as any work area where materials that contain at least 0.1 percent beryllium by weight are processed (1) during any of the operations listed in Appendix A of this Standard, or (2) where employees are, or can reasonably be expected to be, exposed to airborne beryllium at or above the action level. Table A.1 in this appendix sets forth the operations that, where performed under the circumstances described in the column heading above the particular operations, trigger the requirement for a beryllium work area.

TABLE A.1—OPERATIONS FOR ESTABLISHING BERYLLIUM WORK AREAS WHERE PROCESSING MATERIALS CONTAINING AT LEAST 0.1 PERCENT BERYLLIUM BY WEIGHT

Beryllium metal alloy operations (generally <10% beryllium by weight)	Beryllium composite operations (generally >10% beryllium by weight) and beryllium metal operations	Beryllium oxide operations
Abrasive Blasting	Abrasive Blasting	Abrasive Blasting.
Abrasive Processing	Abrasive Processing	Abrasive Processing.
Abrasive Sawing	Abrasive Sawing	Abrasive Sawing.
Annealing	Annealing	Boring.
Bright Cleaning	Atomizing	Brazing (>1,100 °C).
Brushing	Attritioning	Broaching with green ceramic.
Buffing	Blanking	Brushing.
Burnishing	Bonding	Buffing.
Casting	Boring	Centerless grinding.
Centerless Grinding	Breaking	Chemical Cleaning.
Chemical Cleaning	Bright Cleaning	Chemical Etching.
Chemical Etching	Broaching	CNC Machining.
Chemical Milling	Brushing	Cold Isostatic Pressing (CIP).
Dross Handling	Buffing	Crushing.
Deburring (grinding)	Burnishing	Cutting.
Electrical Chemical Machining (ECM)	Casting	Deburring (grinding).
	Centerless Grinding	Deburring (non-grinding).
Electrical Discharge Machining (EDM)	Chemical Cleaning	Destructive Testing.
Extrusion	Chemical Etching	Dicing.
Forging	Chemical Milling	Drilling.
Grinding	CNC Machining	Dry/wet Tumbling.
Heat Treating (in air)	Cold Isostatic Pressing	Extrusion.
High Speed Machining (≤10,000 rpm)	Cold Pilger	Filing by Hand.
Hot Rolling	Crushing	Firing of Green Ceramic.
Lapping	Cutting	Firing of Refractory Metallization (>1,100 °C).
Laser Cutting	Deburring	Grinding.
Laser Machining	Dicing	Honing.
Laser Scribing	Drawing	Hot Isostatic Pressing (HIP).
Laser Marking	Drilling	Lapping.

TABLE A.1—OPERATIONS FOR ESTABLISHING BERYLLIUM WORK AREAS WHERE PROCESSING MATERIALS CONTAINING AT LEAST 0.1 PERCENT BERYLLIUM BY WEIGHT—Continued

Beryllium metal alloy operations (generally <10% beryllium by weight)	Beryllium composite operations (generally >10% beryllium by weight) and beryllium metal operations	Beryllium oxide operations
Melting	Dross Handling	Laser Cutting.
Photo-Etching	Electrical Chemical Machining (ECM)	Laser Machining.
Pickling	Electrical Discharge Machining (EDM)	Laser Scribing.
Point and Chamfer	Extrusion	Laser Marking.
Polishing	Filing by Hand	Machining.
Torch Cutting (i.e., oxy-acetylene)	Forging	Milling.
Tumbling	Grinding	Piercing.
Water-jet Cutting	Heading	Mixing.
Welding	Heat Treating	Plasma Spray.
Sanding	Honing	Polishing.
Slab Milling	Hot Isostatic Pressing (HIP)	Powder Handling.
	Lapping	Powder Pressing.
	Laser Cutting	Reaming.
	Laser Machining	Sanding.
	Laser Scribing	Sectioning.
	Laser Marking	Shearing.
	Machining	Sintering of Green Ceramic.
	Melting	Sintering of refractory metallization (>1,100 °C).
	Milling	Snapping.
	Mixing	Spray Drying.
	Photo-Etching	Tape Casting.
	Pickling	Turning.
	Piercing	Water Jet Cutting.
	Pilger.	
	Plasma Spray.	
	Point and Chamfer.	
	Polishing.	
	Powder Handling.	
	Powder Pressing.	
	Pressing.	
	Reaming.	
	Roll Bonding.	
	Rolling.	
	Sanding.	
	Sawing (tooth blade).	
	Shearing.	
	Sizing.	
	Skiving.	
	Slitting.	
	Snapping.	
	Sputtering.	
	Stamping.	
	Spray Drying.	
	Tapping.	
	Tensile Testing.	
	Torch Cutting (i.e., oxy acetylene).	
	Trepanning.	
	Tumbling.	
	Turning.	
	Vapor Deposition.	
	Water-Jet Cutting.	
	Welding.	

* * * * *

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Part IV

The President

Proclamation 9831—National Pearl Harbor Remembrance Day, 2018

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Presidential Documents

Title 3—

The President

Proclamation 9831 of December 6, 2018

National Pearl Harbor Remembrance Day, 2018

By the President of the United States of America

A Proclamation

Today, we honor those who perished 77 years ago at Pearl Harbor, and we salute every veteran who served in World War II over the 4 years that followed that horrific attack.

On December 7, 1941, America was attacked without warning at Pearl Harbor, Hawaii, by the air and naval forces of Imperial Japan. Just before 8:00 a.m., Japanese aircraft ripped through the sky, dropping bombs on ships of the United States Pacific Fleet and on nearby airfields and bases. The attack took the lives of more than 2,400 American service members and wounded another 1,100 American citizens. The brutal surprise attack halted only after nearly two hours of chaos, death, and destruction.

Despite the shock and confusion of the moment, American service members and first responders on the island of Oahu mounted an incredibly brave defense against insurmountable odds. American pilots took to the air to engage enemy aircraft, sailors took their battle stations, and medical personnel cared for the wounded. Many witnesses to the events of that day perished in the attacks, leaving countless acts of valor unrecorded. Nevertheless, 15 Medals of Honor were awarded—10 of them posthumously—to United States Navy personnel for acts of valor above and beyond the call of duty.

Although the United States Pacific Fleet at Pearl Harbor was badly impaired, America did not falter. One day after the attacks, President Franklin Delano Roosevelt declared to the Congress: ''No matter how long it may take us to overcome this premeditated invasion, the American people in their righteous might will win through to absolute victory.'' And, in the weeks, months, and years that followed the brutal attack at Pearl Harbor, Americans united with a steadfast resolve to defend the freedoms upon which our great Nation was founded. Millions of brave men and women answered their country's call to service with unquestionable courage. These incredible patriots fought, bled, sacrificed, and ultimately triumphed for the cause of freedom.

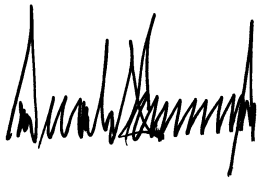
We are blessed as a Nation to have as examples the incredible heroes of World War II, who fought so valiantly to preserve all that we hold dear. Earlier this year, I had the tremendous honor of meeting Mr. Ray Chavez, who was the oldest living Pearl Harbor veteran. Ray passed away only a few weeks ago at the incredible age of 106. But his legacy is forever etched into our country's rich history, along with the legacies of all our brave veterans. They tell of the mettle of the American spirit under fire and of the will of our people to stand up to any threat. The selfless bravery and dedication of these extraordinary Americans will never be forgotten.

Today, we remember all those killed on the island of Oahu on that fateful Sunday morning in 1941, and we honor the American patriots of the Greatest Generation who laid down their lives in the battles of World War II. America is forever blessed to have strong men and women with exceptional courage who are willing and able to step forward to defend our homeland and our liberty.

The Congress, by Public Law 103–308, as amended, has designated December 7 of each year as ''National Pearl Harbor Remembrance Day.''

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby proclaim December 7, 2018, as National Pearl Harbor Remembrance Day. I encourage all Americans to observe this solemn day of remembrance and to honor our military, past and present, with appropriate ceremonies and activities. I urge all Federal agencies and interested organizations, groups, and individuals to fly the flag of the United States at half-staff in honor of those American patriots who died as a result of their service at Pearl Harbor.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of December, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



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S. 2152/P.L. 115–299
Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018 (Dec. 7, 2018; 132 Stat. 4383)
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