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

Rules and Regulations

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FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1238

[No. 2019–N–6]

Orders: Reporting by Regulated Entities of Stress Testing Results as of December 31, 2018; Summary Instructions and Guidance

AGENCY: Federal Housing Finance Agency.

ACTION: Orders.

SUMMARY: In this document, the Federal Housing Finance Agency (FHFA) provides notice that it issued Orders, dated March 5, 2019, with respect to stress test reporting as of December 31, 2018, under section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). Summary Instructions and Guidance accompanied the Orders to provide testing scenarios.

DATES: Each Order is applicable March 5, 2019.

FOR FURTHER INFORMATION CONTACT: Naa Awaa Tagoe, Senior Associate Director, Office of Financial Analysis, Modeling & Simulations, Division of Housing Mission & Goals, (202) 649–3140, *NaaAwaa.Tagoe@fhfa.gov;* Stefan Szilagyi, Examination Manager, Office of Risk Modeling, Division of Bank Regulation (202) 649–3515, *Stefan.Szilagyi@fhfa.gov;* Karen Heidel, Assistant General Counsel, Office of General Counsel, (202) 649–3073, *Karen.Heidel@fhfa.gov;* or Mark D. Laponsky, Deputy General Counsel, Office of General Counsel, (202) 649–3054, *Mark.Laponsky@fhfa.gov.* The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

FHFA is responsible for ensuring that the regulated entities operate in a safe and sound manner, including the maintenance of adequate capital and internal controls, that their operations and activities foster liquid, efficient, competitive, and resilient national housing finance markets, and that they carry out their public policy missions through authorized activities. *See* 12 U.S.C. 4513. These Orders are being issued under 12 U.S.C. 4516(a), which authorizes the Director of FHFA to require by Order that the regulated entities submit regular or special reports to FHFA and establishes remedies and procedures for failing to make reports required by Order. The Orders, through the accompanying Summary Instructions and Guidance, prescribe for the regulated entities the scenarios to be used for stress testing. The Summary Instructions and Guidance also provides to the regulated entities advice concerning the content and format of reports required by the Orders and the rule.

II. Orders, Summary Instructions and Guidance

For the convenience of the affected parties and the public, the text of the Orders follows below in its entirety. The Orders and Summary Instructions and Guidance are also available for public inspection and copying at the Federal Housing Finance Agency's Freedom of Information Act (FOIA) Reading Room at *https://www.fhfa.gov/AboutUs/FOIAPrivacy/Pages/Reading-Room.aspx* by clicking on ''Click here to view Orders'' under the Final Opinions and Orders heading. You may also access these documents at *http://www.fhfa.gov/SupervisionRegulation/DoddFrankActStressTests.*

The text of the Orders is as follows:

Federal Housing Finance Agency

Order Nos. 2019–OR–B–1, 2019–OR–FNMA–1, and 2019–OR–FHLMC–1

Reporting by Regulated Entities of Stress Testing Results as of December 31, 2018

Whereas, section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act'') requires certain financial companies with total consolidated assets of more than $10 billion, and which are regulated by a primary Federal financial regulatory agency, to conduct annual stress tests to determine whether the companies have the capital necessary to absorb losses as a result of adverse economic conditions;

Whereas, FHFA's rule implementing section 165(i)(2) of the Dodd-Frank Act is codified as 12 CFR 1238 and requires that ''[e]ach regulated entity must file a report in the manner and form established by FHFA.'' 12 CFR 1238.5(b);

Whereas, The Board of Governors of the Federal Reserve System issued stress testing scenarios on February 5, 2019; and

Whereas, section 1314 of the Safety and Soundness Act, 12 U.S.C. 4514(a) authorizes the Director of FHFA to require regulated entities, by general or specific order, to submit such reports on their management, activities, and operation as the Director considers appropriate.

Now therefore, it is hereby Ordered as follows:

Each regulated entity shall report to FHFA and to the Board of Governors of the Federal Reserve System the results of the stress testing as required by 12 CFR 1238, in the form and with the content described therein and in the Summary Instructions and Guidance, with Appendices 1 through 12 thereto, accompanying this Order and dated March 5, 2019.

It is so ordered, this the 5th day of March 2019.

This Order is effective immediately.

Signed at Washington, DC, this 5th day of March 2019.

Joseph M. Otting,

Acting Director, Federal Housing Finance Agency.

Dated: July 18, 2019.

Mark A. Calabria,

Director, Federal Housing Finance Agency.

[FR Doc. 2019–15766 Filed 7–24–19; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0116; Product Identifier 2018–NM–152–AD; Amendment 39–19682; AD 2019–14–04]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive fuel airworthiness limitations. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 29, 2019.

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

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0116.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0116; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: 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:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. The NPRM published in the **Federal Register** on March 5, 2019 (84 FR 7835). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive fuel airworthiness limitations.

The FAA is issuing this AD to address the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0231, dated October 25, 2018 (''AD 2018–0231'') (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A318, A319, A320, and A321 series airplanes. The MCAI states:

> The Airworthiness Limitations for the Airbus A320 family aeroplanes, which are approved by EASA, are currently defined and published in the A318/A319/A320/A321 ALS document(s). The Fuel Airworthiness Limitations (FAL) are published in ALS Part 5.
>
> Failure to accomplish these instructions could result in an unsafe condition.
>
> Previously, EASA issued AD 2017–0169 [which corresponds to FAA AD 2018–17–21, Amendment 39–19375 (83 FR 44209, August 30, 2018) (''AD 2018–17–21'')] to require accomplishment of all maintenance tasks and replacement of life limited parts as described in ALS Part 5 at Revision 04.
>
> Since that [EASA] AD was issued, Airbus published the ALS, including new and/or more restrictive requirements, and new A320 family models were certified and added to the Applicability.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2017–0169, which is superseded, expands the Applicability and requires accomplishment of the actions specified in the ALS.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0116.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM

Matthew Flanders, Cristian Silva, and Ben Troike, stated their support for the NPRM. United Airlines (UAL) stated that it fully agrees with the proposed requirements.

Request To Supersede Related AD

UAL requested that we supersede AD 2018–17–21. UAL stated that EASA AD 2018–0231 provides equivalent requirements as the proposed AD. In addition, UAL commented that the requirements in the proposed AD terminates all the requirements in AD 2018–17–21; therefore, the proposed AD should supersede AD 2018–17–21.

The FAA disagrees with issuing this final rule as a supersedure AD. As stated in the NPRM, the FAA determined that a stand-alone AD is more appropriate to address the actions in the MCAI because it is more streamlined for the FAA to release stand-alone ADs, compared to the supersedure ADs. The FAA considered the entire fleet size that would be affected by superseding AD 2018–17–21 and the consequent workload associated with revising maintenance record entries. In light of this, the FAA determined that a less burdensome approach is to issue a separate AD. Further, revising this AD as requested would necessitate (under the provisions of the Administrative Procedure Act) reissuing the notice, reopening the period for public comment, considering additional comments subsequently received, and eventually issuing a final rule. Therefore, in consideration of the unsafe condition, the FAA has determined that further delay of this AD is not appropriate. The FAA has not changed this AD in this regard.

Changes Made to This Final Rule

The FAA has determined that Airbus SAS Model A320–252N airplanes were inadvertently omitted from the Applicability of the proposed AD.

Therefore, the FAA has updated paragraph (c)(3) of this AD to add those airplanes. Since there are currently no domestic operators of this product, additional notice and opportunity for public comment before issuing this AD are unnecessary.

In the ''Costs of Compliance'' paragraph, we have updated the figure to 1,497 airplanes to reflect the current number of airplanes on the U.S. registry.

Conclusion

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

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

Related Service Information Under 1 CFR Part 51

Airbus SAS has issued A318/A319/A320/A321 Airworthiness Limitations Section (ALS), Part 5, Fuel Airworthiness Limitations (FAL), Revision 05, dated June 13, 2018. This service information describes fuel airworthiness limitations items and critical design configuration control limitations (CDCCLs).

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

Costs of Compliance

The FAA estimates that this AD affects 1,497 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD.

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

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–14–04 Airbus SAS: Amendment 39–19682; Docket No. FAA–2019–0116; Product Identifier 2018–NM–152–AD.

(a) Effective Date

This AD is effective August 29, 2019.

(b) Affected ADs

This AD affects AD 2018–17–21, Amendment 39–19375 (83 FR 44209, August 30, 2018) (''AD 2018–17–21'').

(c) Applicability

This AD applies to the Airbus SAS airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before June 13, 2018.

(1) Model A318–111, –112, –121, and –122 airplanes.

(2) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(3) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, and –271N airplanes.

(4) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(d) Subject

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

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address the potential of ignition sources inside fuel tanks, which, in combination with flammable fuel vapors, could result in a fuel tank explosion and consequent loss of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS), Part 5, Fuel Airworthiness Limitations (FAL),

Revision 05, dated June 13, 2018. The initial compliance time for doing the tasks is at the time specified in Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS), Part 5, Fuel Airworthiness Limitations (FAL), Revision 05, dated June 13, 2018, or within 90 days after the effective date of this AD, whichever occurs later.

(h) No Alternative Actions, Intervals, or Critical Design Configuration Control Limitations (CDCCLs)

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

(i) Terminating Action for AD 2018–17–21

Accomplishing the actions required by this AD terminates all requirements of AD 2018–17–21.

(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.*

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

(ii) AMOCs approved previously for AD 2018–17–21 are approved as AMOCs for the corresponding provisions of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests 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) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0231, dated October 25, 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–2019–0116.

(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.

(l) Material Incorporated by Reference

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

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

(i) Airbus A318/A319/A320/A321 Airworthiness Limitations Section (ALS), Part 5, Fuel Airworthiness Limitations (FAL), Revision 05, dated June 13, 2018.

(ii) Reserved

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

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

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

Issued in Des Moines, Washington, on July 16, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–15821 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8501; Product Identifier 2014–SW–042–AD; Amendment 39–19678; AD 2019–13–05]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This AD was prompted by fatigue analysis indicating stress concentrations, as well as the discovery of a helicopter with a crack in the station (STA) 362 frame and skin. This AD requires inspecting the main transmission forward and aft frame assemblies and adjacent skins for a crack and loose fasteners, and establishing life limits for certain frame assemblies. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email: *wcs_cust_service_eng.gr-sik@lmco.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

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–2016–8501; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kristopher Greer, Aviation Safety Engineer, Boston ACO Branch, Compliance and Airworthiness

Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email *Kristopher.Greer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Sikorsky Model S–92A helicopters. The NPRM published in the **Federal Register** on July 15, 2016 (81 FR 46002). The NPRM was prompted by a fatigue analysis that indicates stress concentrations may develop at the steel doublers on the main transmission airframe support structure top deck, adjacent to the transmission feet. Additionally, a helicopter was discovered with a crack in the STA 362 frame and skin. The NPRM proposed to require inspecting the main transmission forward and aft frame assemblies and adjacent skins for a crack and loose fasteners, and replacing or repairing any cracked part or loose fastener. The NPRM also proposed to require establishing life limits for certain frame assemblies.

The FAA issued a supplemental NPRM (SNPRM) (83 FR 66167, December 26, 2018) that proposed to revise the NPRM by increasing the estimated costs of compliance and removing the daily inspection requirements.

The FAA is issuing this AD to detect a crack in a main transmission airframe support structure, which could result in failure of a main transmission frame and subsequent loss of control of the helicopter.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the SNPRM and the FAA's response to each comment.

Request To Reference the Latest Service Information

Sikorsky requested that the FAA reference the latest revision of Sikorsky S–92A–AMM–000 Maintenance Manual, Chapter 53–20–00, Task 53–20–00–210–003, ''Inspection of Main Transmission Airframe Support Structure.''

The FAA agrees. The FAA has revised this final rule to reference Sikorsky S–92A–AMM–000 Maintenance Manual, Chapter 53–20–00, Task 53–20–00–210–003, ''Inspection of Main Transmission Airframe Support Structure,'' dated November 30, 2018.

Request To Revise Certain Terminology in the SNPRM

Sikorsky requested that all instances of ''life limits'' be changed to ''replacement intervals.'' Sikorsky stated that this terminology is consistent with 14 CFR Appendix A to part 29 and the approved airworthiness limitations section of the maintenance manual.

The FAA disagrees. The term ''life limit'' has been used in previous ADs applicable to Sikorsky aircraft and is well understood by the aviation industry. In addition, the use of life limit conveys the mandatory nature of the replacement intervals. The FAA has not changed this final rule in this regard.

Request To Revise the Life Limit Hours Time-In-Service (TIS) in the SNPRM

Sikorsky requested that the FAA revise the values for the life limit hours TIS. Sikorsky stated that the replacement intervals for the frame assembly part numbers shown in table 1 to paragraph (e)(1) of the SNPRM (which is referred to as figure 1 to paragraphs (a) and (e) in this final rule) increased since issuance of the NPRM. Sikorsky also stated that a recent certification effort for these parts increased the replacement intervals by a minimum of 7,900 hours, to as much as 17,400 hours, above the limits proposed in the SNPRM. Sikorsky commented that incorporation of these new replacement intervals (ranging from 18,300 life limit hours TIS to 29,400 life limit hours TIS, as applicable) will avoid unnecessary removal from service of frame assemblies and avoid the need for issuance of alternate methods of compliance to address differences between the life limits proposed by the SNPRM and those subsequently approved by the FAA.

The FAA agrees. The FAA has revised the life limits in this final rule for the reasons provided by the commenter because these longer life limits have been approved by the FAA.

Sikorsky further commented that with approval of recent certification work, Forward STA 328 frame assemblies that are altered and changed to P/N 92070–20124–064, 92070–20124–067, 92070–20127–045, 92070–20124–065, 92070–20124–047, or 92070–20127–046 are no longer counted from TIS of alternation. They are only counted from the original frame part number initial service date instead. These part-numbered assemblies were proposed in the SNPRM for removal from service upon accumulating 12,000 hours TIS from the alteration or 28,500 hours TIS total (regardless of part number) from the total original frame part number initial service date, whichever occurs first.

The FAA agrees and has omitted ''remove from service of upon accumulating 12,000 hours TIS from the alteration'' in this final rule.

Additional Changes Made in This Final Rule

The four tables in the SNPRM have been re-identified as figures in this AD. The FAA has also relocated these figures to all follow paragraph (a) of this AD.

FAA's Determination

The FAA has reviewed the relevant information, considered the comments received, and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of the same type design and that air safety and the public interest require adopting the AD requirements as proposed with the changes described previously. These changes are consistent with the intent of the proposals in the SNPRM and do not add any additional burden upon the public than was already proposed in the SNPRM. Additionally, these changes will not increase the economic burden on any operator or increase the scope of the AD.

Related Service Information

Sikorsky issued Alert Service Bulletin (ASB) 92–53–008, Basic Issue, dated June 13, 2012 (ASB 92–53–008); ASB 92–53–009, Basic Issue, dated December 6, 2012 (ASB 92–53–009); ASB 92–53–012, Basic Issue, dated February 10, 2014 (ASB 92–53–012); and S–92A–AMM–000 Maintenance Manual, Chapter 53–20–00, Task 53–20–00–210–003, ''Inspection of Main Transmission Airframe Support Structure,'' dated November 30, 2018 (Task 53–20–00–210–003).

ASB 92–53–008 provides procedures for a one-time inspection of the main transmission frames and beams for a crack, missing or loose fastener or collar, damage, deformation, and corrosion. ASB 92–53–009 specifies, among other actions, a recurring 150-hour inspection of the interior and exterior surfaces of the upper flanges and beams. ASB 92–53–012 specifies altering the forward and aft transmission support frames by removing steel doublers, cold-working the holes, oversizing the holes, trimming skin panels, and reassembling the parts with interference fit fasteners in accordance with Special Service Instructions 92–074–E. After this alteration, the parts are re-identified with a new part number. Sikorsky refers to this alteration as a service life

extension program modification. Task 53–20–00–210–003 describes procedures for an inspection of the main transmission airframe support structure.

Differences Between This AD and the Service Information

The service information recommends providing certain information to Sikorsky, and this AD does not. The service information specifies performing a fluorescent penetrant inspection if there is a suspected crack and contacting Sikorsky if there is a crack, while this AD only requires repairing or replacing any cracked part. Contacting Sikorsky is not required by this AD.

Costs of Compliance

The FAA estimates that this AD affects 50 helicopters of U.S. Registry. The FAA estimates that operators may incur the following costs to comply with this AD. Labor costs are estimated at $85 per work-hour.

The FAA estimates a minimal cost to establish and revise the life limit of the frame assembly. The FAA estimates it takes 1 work-hour to inspect STA 328 and 362 frames. No parts are needed for a total cost of $4,250 for the U.S. fleet for each inspection per inspection cycle. If a fastener is replaced, the FAA estimates the cost to be minimal. If a frame is replaced, it takes 5,000 work-hours and required parts cost $296,000 for a total cost of $721,000 per helicopter.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–13–05 Sikorsky Aircraft Corporation: Amendment 39–19678; Docket No. FAA–2016–8501; Product Identifier 2014–SW–042–AD.

(a) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–92A helicopters, certificated in any category, with a forward station (STA) 328 or aft STA 362 frame assembly with a part number (P/N) as shown in Figure 1 to paragraphs (a) and (e) of this AD, Figure 2 to paragraphs (a) and (e) of this AD, Figure 3 to paragraphs (a) and (e)(2) of this AD, or Figure 4 to paragraphs (a) and (e)(2) of this AD.

BILLING CODE 4910–13–P

Figure 1 to Paragraphs (a) and (e)

Forward STA 328 Frame Assembly P/N	Life Limit Hours TIS
92070-20124-064	28,500
92070-20124-067	28,500
92070-20127-045	28,500
92070-20124-065	28,500
92070-20124-047	28,500
92070-20127-046	28,500
92070-20124-063	29,400
92070-20124-066	29,400
92070-20127-041	29,400
Aft STA 362 Frame Assembly P/N	**Life Limit Hours TIS**
92070-20124-041	18,300
92070-20124-044	18,300
92070-20127-042	18,300
92070-20124-042	18,300
92070-20124-045	18,300
92070-20127-049	18,300
92070-20124-043	18,300
92070-20124-046	18,300
92070-20127-050	18,300
92070-20141-050	27,600
92070-20141-051	27,600
92070-20141-052	27,600

Figure 2 to Paragraphs (a) and (e)

Forward STA 328 Frame Assembly P/N	Life Limit Hours TIS
92070-20097-058	28,500
92080-20047-047	28,500
92070-20097-060	28,500
92080-20047-048	28,500

Figure 3 to Paragraphs (a) and (e)(2)

Forward STA 328 Frame Assembly P/N	Aft STA 362 Frame Assembly P/N
92209-02106-042	92070-20097-062
92209-02106-043	92080-20047-051
92070-20097-041	92209-02109-043
92080-20047-041	92209-02109-044
	92070-20097-042
	92080-20047-042
	92070-20097-064
	92080-20047-052

Figure 4 to Paragraphs (a) and (e)(2)

Forward STA 328 Frame Assembly P/N	Aft STA 362 Frame Assembly P/N
92209-02107-042	92209-02108-042
92209-02107-103	92209-02108-103

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(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a main transmission airframe support structure. This condition could result in failure of a main transmission frame and subsequent loss of control of the helicopter.

(c) Effective Date

This AD is effective August 29, 2019.

(d) Compliance

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

(e) Required Actions

(1) For helicopters with a frame assembly with a part number shown in Figure 1 to paragraphs (a) and (e) of this AD or Figure 2 to paragraphs (a) and (e) of this AD, before further flight, remove from service any part that has reached or exceeded its new life limit. Forward STA 328 frame assemblies that are altered and changed to P/N 92070–20124–064, 92070–20124–067, 92070–20127–045, 92070–20124–065, 92070–20124–047, or 92070–20127–046 must be removed from service upon accumulating 28,500 hours time-in-service (TIS) total (regardless of P/N) from the original frame part number initial service date.

(2) For each frame assembly listed in Figure 1 to paragraphs (a) and (e) of this AD or Figure 4 to paragraphs (a) and (e)(2) of this AD with 1,801 or more hours TIS, and for each frame assembly listed in Figure 2 to paragraphs (a) and (e) of this AD or Figure 3 to paragraphs (a) and (e)(2) of this AD with 1,301 or more hours TIS, within 150 hours TIS and thereafter at intervals not to exceed 150 hours TIS, do the following inspections. For guidance on performing these inspections, refer to Sikorsky S–92A–AMM–000 Maintenance Manual Chapter 53–20–00, Task 53–20–00–210–003, ''Inspection of Main Transmission Airframe Support Structure,'' dated November 30, 2018.

(i) Inspect the STA 328 frame and STA 362 frame between the left and right butt line (BL) 16.5 beams and inspect the area on the left and right BL 16.5 beams six inches on either side of the mounting pads for a crack and loose fasteners. If there is a loose fastener or a crack, repair or replace any cracked part and any loose fastener before further flight.

(ii) Inspect the STA 328 and STA 362 outboard frames, left and right sides, from the BL 16.5 beam to water line 252.25 for a crack and loose fasteners. If there is a loose fastener or a crack, repair or replace any cracked part and any loose fastener before further flight.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Kristopher Greer, Aviation Safety Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7799; email *Kristopher.Greer@faa.gov.*

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

(g) Additional Information

Sikorsky Alert Service Bulletin (ASB) 92–53–008, Basic Issue, dated June 13, 2012; ASB 92–53–009, Basic Issue, dated December 6, 2012; ASB 92–53–012, Basic Issue, dated February 10, 2014, Sikorsky Special Service Instructions No. 92–074–E, Revision E, dated April 9, 2014, and Sikorsky S–92A–AMM–000 Maintenance Manual, Chapter 53–20–00, Task 53–20–00–210–003, ''Inspection of Main Transmission Airframe Support Structure,'' dated November 30, 2018, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–Winged–S or 203–416–4299; email *wcs_cust_service_eng.gr-sik@lmco.com.* You may view this information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft System Component (JASC) Code: 5311, Fuselage Main, Frame.

Issued in Fort Worth, Texas, on July 10, 2019.

James A. Grigg,

Acting Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019–15757 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0222; Airspace Docket No. 19–ASW–5]

RIN 2120–AA66

Establishment of Class E Airspace; Beeville-Chase Field, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Chase Field Industrial Airport, Beeville-Chase Field, TX. Controlled airspace is necessary to accommodate new standard instrument approach procedures developed at Chase Field Industrial Airport, for the safety and management of instrument flight rules (IFR) operations.

DATES: Effective 0901 UTC, October 10, 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 *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

On April 5, 2019, the FAA published a notice of proposed rulemaking in the **Federal Register** (84 FR 13574) for Docket No. FAA–2019–0222, to establish Class E airspace extending upward from 700 feet above the surface at Chase Field Industrial Airport, Beeville-Chase Field, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Three comments were received all in favor of the new Class E airspace.

Availability and Summary of Documents for Incorporation by Reference

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

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Chase Field Industrial Airport, Beeville-Chase Field, TX, to accommodate new standard instrument approach procedures developed for the airport, for the safety and management of instrument flight rules (IFR) operations.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

* * * * *

ASW TX E5 Beeville-Chase Field, TX [New]

Chase Field Industrial Airport, TX
(Lat. 28°21′45″ N, long. 097°39′43″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Chase Field Industrial Airport.

Issued in Fort Worth, Texas, on July 18, 2019.

John Witucki,

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

[FR Doc. 2019–15758 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 135

[Docket No.: FAA–2019–0564; Amendment No. 135–141]

RIN 2120–AK94

IFR Operations at Locations Without Weather Reporting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is amending a regulation to allow helicopter air ambulance (HAA) operators to conduct instrument flight rules departure and approach procedures at airports and heliports that do not have an approved weather reporting source. This rule applies to HAA aircraft without functioning severe weather detection equipment (airborne radar or lightning strike detection equipment), to permit instrument flight rules departure and approach procedures when the pilot in command reasonably determines that the operation will not encounter severe weather at the destination, the alternate destination, or along the route of flight. This amended rule also updates requirements to address the discontinuance of area forecasts and certain requirements concerning HAA departure procedures.

DATES: This final rule is effective August 26, 2019.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How To Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Tom Luipersbeck, Air Transportation Division, 135 Air Carrier Operations Branch, AFS–250, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–267–8166; email: *Thomas.A.Luipersbeck@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This rule finalizes the notice of proposed rulemaking entitled *IFR Operations at Locations Without Weather Reporting* (the NPRM).[1] The NPRM proposed permitting HAA departure and approach procedures conducted under instrument flight rules (IFR) when helicopters do not have functional severe weather detection equipment and when the airport or heliport at which the departure or approach will occur does not have an approved weather reporting source. The proposed regulatory text specified that such procedures could only occur when the pilot in command does not expect to encounter severe weather at the destination, the alternate destination, or along the route of flight. The NPRM further proposed updates to address the transition from Area Forecasts that the National Weather Service (NWS) currently provides to equivalent information from weather reports, forecasts, or any combination thereof. In addition, the NPRM proposed amending the term ''the published Obstacle Departure Procedure'' to ''a published departure procedure.'' This rule finalizes all amendments the NPRM included, with no modifications.

II. Background

A. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is codified in Title 49 of the United States Code. The FAA promulgates this rule under the general authority described in 49 U.S.C. 106, which includes a detailed description of the agency's authority. Section 106(f) establishes that the Administrator may promulgate and revise regulations as are necessary to carry out the FAA's functions. Furthermore, § 44701(a) requires the Administrator to promote safe flight of civil aircraft in air commerce by prescribing regulations and setting minimum standards for other practices, methods and procedures necessary for safety in air commerce and national security. Moreover, § 44730 addresses HAA operations and authorizes the Administrator to engage in rulemaking to ensure safety of part 135 certificate holders that engage in such operations.

B. Comments in Response to Proposed Rule

The FAA received five comments in response to the NPRM, all of which support the proposed amendment to remove the requirement for severe weather detection equipment in 14 CFR 135.611(b). The commenters generally agreed with the FAA that the amendment will encourage pilots to fly under IFR, which is safer than flights operated under visual flight rules (VFR), for flights conducted under marginal VFR conditions. One comment from an individual suggested the FAA consider further changes, such as requiring utilization of ''lower altitude airway structures'' and modifications to rules concerning operations in icing conditions. The FAA appreciates the suggestions, but finds that such amendments to the final rule would be outside the scope of the proposal.

The Air Medical Operators Association (AMOA) requested the FAA clarify in the final rule that the use of the term ''airport'' in § 135.611 includes heliports. The FAA agrees that the term ''airport,'' as defined in 14 CFR 1.1 and as used throughout the FAA's regulations, means an area of land or water that is used or intended to be used for the landing and takeoff of aircraft. This definition is broad, and includes heliports.

Additionally, AMOA supported the proposed amendment to remove the word ''obstacle'' from the term ''obstacle departure procedure'' in § 135.611(a)(3). The FAA agrees with AMOA that updating the term to ''departure procedure'' is necessary in order to permit the use of other departure procedures. For example, operators may conduct a diverse departure procedure or standard instrument departure procedure that the FAA has deemed safe and appropriate based on ensured obstacle clearance and flyability.

No commenters addressed the FAA's proposal to update the text of § 135.611(a)(1) to address the transition from Area Forecasts that the NWS currently provides to equivalent information from weather reports, forecasts, or any combination of such sources.

C. Exemption History

Since the FAA established the requirement for HAA operators to use helicopters equipped with functioning severe weather detection equipment, the FAA has received ten petitions for exemption from the requirement.[2] These HAA operators established in their petitions that an exemption would not adversely affect safety because they would not conduct operations in accordance with the exemption if they expected to encounter severe weather

[1] 83 FR 15332 (Apr. 10, 2018).

[2] The FAA issued the final rule that set forth the requirement of § 135.611(b) on July 28, 2014. 79 FR 43622. Any certificate holder that seeks exemption from such a requirement may submit a petition for exemption pursuant to 14 CFR 11.81.

conditions along their intended route of flight.[3] As a result, the FAA issued exemptions to those HAA operators, which allowed the safe conduct of IFR departure and approach procedures at airports that do not have an approved weather reporting source and when the helicopter used does not have severe weather detection equipment (airborne radar or lightning strike detection equipment). Each grant of exemption is valid for two years, unless sooner superseded or rescinded by the FAA. As a result, exemption holders need to seek renewal of their exemptions on a periodic basis.

III. Discussion of the Final Rule

A. Operations at Locations Without an Approved Weather Reporting Source

The FAA's initial intent of requiring severe weather detection equipment was to help the pilot ascertain the weather in the aircraft's vicinity.[4] The FAA then determined requiring such equipment, which includes radar or lightning strike detection equipment, would reduce the chances of a pilot inadvertently encountering instrument meteorological conditions (IMC). As noted in the NPRM, the FAA has since determined this requirement is overly broad, because it applies even in circumstances in which the pilot does not reasonably expect to encounter severe weather along the route or at the destination.

Training, preflight evaluation of weather data, and risk analysis procedures all ensure pilots are adequately skilled in reasonably determining whether severe weather might exist at the destination, the alternate destination, or along the route of flight. The requisite training that pilots undergo on meteorology ensures pilots have practical knowledge of weather phenomena, including the principles of frontal systems, icing, fog, thunderstorms, and meteorology hazards applicable to the certificate holder's areas of operation. Further, pilots who conduct HAA operations receive training on adverse weather avoidance practices and weather planning. This training, together with the pre-flight risk analysis required in § 135.617, ensures pilots in command will reasonably ascertain if severe weather may exist along the route of a flight or at the destination airport. Moreover, pilots in command conduct risk analyses prior to each flight, which include determining whether another HAA operator has rejected a similar flight request based on the presence of any severe weather or dangerous meteorological phenomena. Overall, the pilot in command will use the knowledge and skills he or she maintains pursuant to the provisions of subpart L of part 135 in determining the likelihood of encountering severe weather. These requirements obviate the need for severe weather detection equipment when he or she does not reasonably expect to encounter severe weather.

As the FAA explained in the NPRM, § 135.611(b) inadvertently restricted HAA operations conducted when no severe weather is present at the airport or along the route.[5] Therefore, the FAA anticipates this amendment will increase the number of IFR operations because the IFR infrastructure would be available to more operators. Such an increase in the frequency of IFR operations will minimize operations under VFR while in marginal visual meteorological conditions, and thereby increase safety.

The FAA emphasizes, however, that if a reasonable expectation of severe weather exists prior to or during the flight, at the destination, the alternate destination, or along the route of flight, the helicopter must be equipped with functioning severe weather detection equipment. In the absence of such equipment, the pilot in command must decline the flight, as appropriate.

B. Area Forecasts

The FAA, in coordination with the NWS, expects to discontinue Area Forecasts, currently used as flight planning and pilot weather briefing aids and transition to digital and graphical alternatives already being produced by NWS.[6] While the Area Forecast met aviation weather information needs for many years, today the NWS provides equivalent information through a number of other reliable alternatives.[7] NWS is currently engaged in transitioning Area Forecasts, which pilots currently use for flight planning and weather briefing aids, to digital and graphical alternatives. In order to address this upcoming transition, this rulemaking updates the wording of § 135.611(a)(1) from ''area forecast'' to ''weather reports, forecasts, or any combination of them.''

C. Departure Procedures

This rule also updates requirements in § 135.611 regarding HAA departure procedures (DP) to include additional types of DP that are currently acceptable for use. A DP is necessary when a pilot in command intends to depart from an airport in weather conditions less than VFR. Several types of DPs, however, exist in addition to an ''obstacle departure procedure'' cited in the current regulation. For example, pilots in command may use a diverse DP or standard instrument DP. Based on an evaluation of the potential departure procedures, the FAA has determined that any of these DPs may be appropriate and safe, based on ensured obstacle clearance and flyability. Overall, removing the word ''obstacle'' permits additional types of DPs, such as departures from an airport in weather conditions that are less than VFR.

While this rule increases flexibility, it does not decrease the level of safety of HAA departures. The pilot in command remains responsible for using such an alternate procedure only after determining it is appropriate for the location of departure. Accordingly, the FAA amends the wording in § 135.611(a)(3) from ''the published Obstacle Departure Procedure'' to ''a published departure procedure.''

IV. Regulatory Notices and Analyses

A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 prohibits agencies from setting standards that create unnecessary obstacles to the

[3] See the following FAA grants of petitions for exemption: Docket Nos. FAA–2016–5575, FAA–2016–5028, FAA–2016–2254, FAA–2015–3934, FAA–2015–3854, FAA–2015–3740, FAA–2015–2696, FAA–2015–2694, FAA–2015–1868, and FAA–2015–1867. These exemptions are accessible at *www.regulations.gov.*

[4] *Air Ambulance and Commercial Helicopter Operations, Part 91 Helicopter Operations, and Part 135 Aircraft Operations; Safety Initiatives and Miscellaneous Amendments,* 75 FR 62640, 62650 (Oct. 12, 2010).

[5] 83 FR at 15333.

[6] *Aviation Weather Product Change: Transition of Select Area Forecasts (FAs) to Digital and Graphical Alternatives,* 79 FR 35211 (June 19, 2014). In the Notice, the FAA recommended that NWS transition six area forecasts (FA) covering separate geographical areas of the contiguous United States and one area forecast covering Hawaii to digital and graphical alternatives already being produced by NWS. The following FAs affected by this transition include FAUS41 (BOS), FAUS42 (MIA), FAUS43 (CHI), FAUS44 (DFW), FAUS45 (SLC), and FAUS46 (SFO). *See Information for Operators 17013, Retirement of the NWS FA for the Contiguous United States* (Aug. 28, 2017), *available at https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/info/all_infos/.*

[7] See *id.*

foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995).

The FAA determined this rule would result in cost savings with no reduction in safety and no additional costs. This rule removes unnecessary limits on certain HAA operations. These limits effectively reduced the number of HAA operations without improving aviation safety.[8] In the U.S., there are 65 authorized HAA certificate holders utilizing 1,208 approved air ambulance helicopters that may receive regulatory relief from this rule by allowing certain HAA operations that were previously restricted. In addition, the FAA has granted exemptions to HAA operators who asked for relief from these limitations. This rule would also provide savings by avoiding the need to petition and issue exemptions.

The FAA received five comments in response to the NPRM, all of which support the amendment to remove the requirement for severe weather detection equipment in § 135.611(b). As previously discussed, the commenters agreed with the FAA that the amendment will encourage pilots to fly under IFR, which is safer than flights operated under VFR, for flights conducted under marginal VFR conditions. The FAA did not receive comments on the Regulatory Evaluation in the NPRM. This rule finalizes all amendments the NPRM included, with no modifications.

The FAA was able to quantify a small savings to HAA operators and the FAA from avoided administrative costs associated with processing future petitions for exemptions. As presented in the NPRM, the FAA estimates the avoided administrative costs of submitting and reviewing a petition of exemption, including a renewal, to be about $1,500/exemption for both HAA operators and the FAA based on information from the FAA's Flight Standards Service. The FAA estimates this rule will avoid five exemptions, including renewals, per year.[9] This amounts to $7,500 of savings to HAA operators and the FAA per year. Over a five-year period, the total present value savings from avoided administrative costs associated with petitions is about $34,000 at a three percent discount rate or about $31,000 at a seven percent discount rate.

As previously discussed, this rule will also result in qualitative safety benefits by increasing the number of IFR operations because the IFR infrastructure would be available and used by more operators. Increasing the frequency of IFR operations would minimize operations under VFR while in marginal visual meteorological conditions, and thereby increase aviation safety.

The FAA has determined this final rule provides small cost savings and improved safety benefits and is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' *Id.* section 2(b). The Regulatory Flexibility Act covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions. Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency does not expect a rule to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As this final rule removes an unnecessary limitation on the operation of HAAs without reducing aviation safety, it will relieve HAA operators and the FAA the costs associated with future petitions. This rule will have a positive impact on affected small entities. Any such impact, however, will not be significant. Therefore, the head of the agency certifies the FAA does not expect this rule to have a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979, Public Law 96–39, 93 Stat. 144 (July 26, 1979), as amended by the Uruguay Round Agreements Act, Public Law 103–465, 108 Stat. 4809 (Dec. 8, 1994), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this rule and determined that the rule will have the same impact on international and domestic flights and is a safety rule. Accordingly, the FAA has determined this final rule is consistent with the Trade Agreements Act.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 64 (Mar. 22, 1995), requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

[8] There is a high degree of data uncertainty regarding the number of HAA operations affected by this rule. The FAA did not identify data to quantify the potential benefits and savings from removing limitations on HAA Operations.

[9] From 2015 to 2016, the FAA granted ten petitions for exemption to HAA operators; about five such exemptions per year require renewal. As previously discussed, each grant of exemption is valid for two years, unless sooner superseded or rescinded by the FAA. As a result, current exemption holders need to seek renewal of their exemptions on a periodic basis.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995), requires the FAA consider the impact of any information collection burdens imposed on the public. 44 U.S.C. 3507(d). The FAA has determined that there would be no new requirement for information collection associated with this rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that this rule does not contravene any ICAO Standards and Recommended Practices.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances.[10] The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132, Federalism (Aug. 4, 1999). The agency has determined this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

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

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

C. Executive Order 13609, International Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation (May 1, 2012), promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action will have no effect on international regulatory cooperation.

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

This final rule is a deregulatory action under Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017). Details on the cost savings of this rule are in the Regulatory Evaluation section, as previously noted.

VI. Additional Information

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

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies web page at *http://www.faa.gov/regulations_policies* or

3. Accessing the Government Printing Office's web page at *http://www.gpo.gov/fdsys/.*

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

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the Federal eRulemaking Portal referenced in item (1) above.

List of Subjects in 14 CFR Part 135

Air transportation, Aircraft, and Aviation safety.

The Amendment

In consideration of the foregoing, the FAA amends chapter I of title 14, Code of Federal Regulations as follows:

PART 135—OPERATING REQUIREMENTS: COMMUTER AND ON DEMAND OPERATIONS AND RULES GOVERNING PERSONS ON BOARD SUCH AIRCRAFT

■ 1. The authority citation for part 135 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 41706, 44701–44702, 44705, 44709, 44711–44713, 44715–44717, 44722, 44730, 45101–45105; Pub. L. 112–95, 126 Stat. 58.

■ 2. Amend § 135.611 by revising paragraphs (a)(1) and (3) and (b) to read as follows:

§ 135.611 IFR operations at locations without weather reporting.

(a) * * *

(1) The certificate holder must obtain a weather report from a weather reporting facility operated by the NWS, a source approved by the NWS, or a source approved by the FAA, that is located within 15 nautical miles of the airport. If a weather report is not available, the certificate holder may obtain weather reports, forecasts, or any combination of them from the NWS, a source approved by the NWS, or a source approved by the FAA, for information regarding the weather observed in the vicinity of the airport;

* * * * *

(3) In Class G airspace, IFR departures with visual transitions are authorized only after the pilot in command determines that the weather conditions at the departure point are at or above takeoff minimums depicted in a published departure procedure or VFR minimum ceilings and visibilities in accordance with § 135.609.

* * * * *

(b) Each helicopter air ambulance operated under this section must be equipped with functioning severe weather detection equipment, unless the pilot in command reasonably determines severe weather will not be encountered at the destination, the alternate destination, or along the route of flight.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44730 in Washington, DC, on July 17, 2019.

Daniel K. Elwell,

Acting FAA Administrator.

[FR Doc. 2019–15840 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–13–P

[10] U.S. Department of Transportation, FAA, *Environmental Impacts: Policies and Procedures* (July 16, 2015), *available at https://www.faa.gov/documentLibrary/media/Order/FAA_Order_1050_1F.pdf.*

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 45 and 46

[Docket No. RM18–15–001; Order No. 856–A]

Interlocking Officers and Directors; Requirements for Applicants and Holders

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Order on rehearing.

SUMMARY: In this order on rehearing, the Federal Energy Regulatory Commission grants in part and denies in part rehearing and clarification regarding certain revisions to its regulations related to interlocking officers and directors.

DATES: This order on rehearing will become effective September 23, 2019.

FOR FURTHER INFORMATION CONTACT:
Lindsay Orphanides (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8372, *lindsay.orphanides@ferc.gov*
Mary Ellen Stefanou (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8989, *mary.stefanou@ferc.gov*

SUPPLEMENTARY INFORMATION:

I. Background

1. On February 21, 2019, the Commission issued Order No. 856.[1] Order No. 856 revised parts 45 and 46 of the Commission's regulations related to interlocking officers and directors to clarify and update the requirements for both applicants and holders. In particular, Order No. 856: (1) Updated the Commission's regulations to reflect statutory changes to the circumstances in which an applicant who would otherwise require Commission authorization to hold an interlocking position need not do so; (2) revised the Commission's regulations and clarified the Commission's position on late-filed applications and informational reports; (3) revised the Commission's regulations and clarified that an interlock holder is not required to file a notice of change when merely changing positions within a holding company; (4) revised the Commission's regulations and stated that applicants do not need to list in their applications public utilities that do not have officers or directors; (5) revised the Commission's regulations with regard to public utilities owned by a natural person; (6) created an exemption from the filing requirements for interlocking positions of 90 days or less; and (7) removed § 46.2(b) of the Commission's regulations, which contained definitions and phrases now rendered obsolete.

2. On March 25, 2019, El Paso Electric Company (El Paso) filed a request for rehearing of Order No. 856, seeking clarification or rehearing of two revisions made by the final rule. We address these issues below.

II. Discussion

A. Sufficiency of Form No. 561 for Reporting Changes in Position

1. Final Rule

3. In Order No. 856, the Commission amended §§ 45.4 and 45.5 of the Commission's regulations to state that supplemental applications and notices of change need not be filed in the case of a person already authorized to hold interlocks identified in § 45.9(a) who may assume new or different positions that are still among those identified by § 45.9(a). The Commission stated that such changes in positions among related public utilities are already reported in the annual Form No. 561s,[2] and separate filings under § 45.4 or § 45.5 are unnecessary.

2. Request for Rehearing

4. El Paso seeks clarification that supplemental applications and notices of change need not be filed in the case of a person already authorized to hold interlocks with respect to all interlocks authorized under part 45 generally, and is not limited solely to interlocks identified in § 45.9. El Paso states that, when an officer or director holds a new or different interlocking position within any interlock authorized under part 45, it is reported in Form No. 561. El Paso asserts that ''the Commission's rationale for its clarification in Order No. 856 that Form No. 561 reporting is sufficient, and that supplemental applications and changes in notice need not be filed if/when an officer or director assumes a new or different position within the same interlocking companies, applies equally to any interlock authorized under [p]art 45, and not merely to an interlock identified in [§] 45.9.'' [3]

5. El Paso states that, in the alternative, it seeks rehearing of Order No. 856 and requests that the Commission grant equal treatment to all interlocks authorized under part 45, on the basis that it is sufficient for changes in position for all authorized interlocks to be reported annually in Form No. 561, without the need for the filing of a supplemental application under § 45.4 or a notice of change under § 45.5.[4]

3. Commission Determination

6. We deny El Paso's request for clarification or rehearing. The Commission's rationale for the change adopted in Order No. 856 that supplemental applications and notices of change need not be filed in the case of a person already authorized to hold interlocks identified in § 45.9(a) stated that ''such changes in positions among *related public utilities* are already reported in the annual Form No. 561s, and separate filings under § 45.4 or § 45.5 are unnecessary.'' [5] However, that rationale does not apply equally to ''any interlock authorized under [p]art 45.'' [6] The Commission has recognized a difference between holding interlocks among two or more commonly-owned or -controlled public utilities, and holding an interlock between, for example, a public utility and an electrical equipment supplier. Interlocks that fall under § 45.2 and are not between two or more commonly-owned or -controlled public utilities (and therefore are outside the scope of § 45.9(a)) are reviewed by the Commission so that the Commission can be sure that the ''evils to be eliminated by the enactment of section 305(b)'' [7] are not present. By contrast, for interlocks that fall under § 45.9(a)'s automatic

[1] *Interlocking Officers and Directors; Requirements for Applicants and Holders,* Order No. 856, 84 FR 7274 (March 4, 2019), 166 FERC ¶ 61,119 (2019).

[2] 18 CFR 131.31 (Annual Report of Interlocking Positions). The Form No. 561 is an annual report of information detailing electric public utility officer and board of director positions that officers and directors held within and outside their affiliated public utility at any point during the preceding year.

[3] El Paso Request for Rehearing at 4.

[4] *Id.* (internal citations omitted).

[5] Order No. 856, 166 FERC ¶ 61,119 at P 12 (emphasis added).

[6] El Paso Request for Rehearing at 4.

[7] *James S. Pignatelli,* 111 FERC ¶ 61,496, at P 12 (2005) (quoting *John Edward Aldred,* 2 FPC 247, 261 (1940)). The ''evils to be eliminated by the enactment of section 305(b),'' include: ''[. . .] (3) the lack of arm's-length dealings between public utilities and organizations furnishing financial services or electrical equipment; (4) the employment of dummy directors designated solely for the purpose of executing the order of those in control, and nominal directors who give little time and attention to the affairs of the companies; and (5) violations of laws, ethics, and good business practices by those holding such interlocking positions whereby such relationship is employed for their own benefit or profit, or for the benefit or profit of any other person or persons and to the detriment of the companies, their security holders or the public interest.'' *Id.; accord Hatch* v. *FERC,* 654 F.2d 825, 831–32 (D.C. Cir. 1981).

authorization, the Commission has found that the evils to be eliminated by the enactment of Federal Power Act (FPA) section 305(b) are not present because the potential for abuse would be unlikely to result from such interlocks.[8] Therefore, we will continue to require an officer or director who seeks a new or different interlocking position, or leaves a position, with entities covered by § 45.2 and not subject to the automatic authorization of § 45.9(a) to file supplemental applications and notices of change so that the Commission may review the new or different position to ensure that there continues to be no potential for abuse.

B. Past Grants of Authorization for Interlocks That No Longer Require Commission Authorization

1. Final Rule

7. In Order No. 856, the Commission explained that § 45.2 of the Commission's regulations describes the types of interlocking positions that require Commission authorization, including those between a public utility and entities authorized by law to underwrite or participate in the marketing of public utility securities.[9] However, in 1999, Congress amended FPA section 305(b)(2) to provide that an applicant for certain interlocking positions is no longer required to obtain Commission authorization to hold such positions.[10] In Order No. 856, consistent with the revision of the underlying statute, the Commission revised § 45.2 of its regulations to add that an applicant for an interlocking position between a public utility and a ''bank, trust company, banking association, or firm that is authorized by law to underwrite or participate in the marketing of public utility securities'' [11] does not need Commission authorization when certain circumstances are present; that is, when:

- The person does not participate in any deliberations or decisions of the public utility regarding the selection of the bank, trust company, banking association, or firm to underwrite or participate in the marketing of securities of the public utility, if the person serves as an officer or director of a bank, trust company, banking association, or firm that is under consideration in the deliberation process;
- the bank, trust company, banking association, or firm of which the person is an officer or director does not engage in the underwriting of, or participate in the marketing of, securities of the public utility of which the person holds the position of officer or director;
- the public utility for which he/she serves or proposes to serve as an officer or director selects underwriters by competitive procedures; or
- the issuance of securities of the public utility for which the person serves or proposes to serve as an officer or director has been approved by all Federal and State regulatory agencies having jurisdiction over the issuance.[12]

2. Request for Rehearing

8. El Paso states that a member of its board of directors sought and received Commission approval for an interlock that was subsequently removed from the Commission's FPA jurisdiction as a result of the Gramm-Leach-Bliley Act. El Paso states that ''[t]he presence of this, and other, past grants of case-specific authorizations for interlocks no longer within the Commission's Federal Power Act jurisdiction creates the potential for confusion and uncertainty regarding whether those past applicants are expected to adhere to the requirements of [p]art 45 of the Commission's regulations governing Commission-approved interlocks.'' El Paso therefore seeks the Commission's grant of clarification in this regard, or, in the alternative, rehearing of Order No. 856.[13]

3. Commission Determination

9. We grant El Paso's request for clarification and clarify that if, as a result of the change in FPA section 305(b)(2) in 1999 and the corresponding changes to § 45.2 of the Commission's regulations made by Order No. 856, an individual no longer holds an interlock that requires Commission authorization, that individual no longer needs to adhere to the requirements of parts 45 and 46 of the Commission's regulations governing Commission approval of such interlocks. We direct those individuals holding interlocking positions that no longer require Commission authorization to make a notice of change filing under § 45.5 of the Commission's regulations, within 45 days of the effective date of this order, informing the Commission that they no longer hold such interlocks.

III. Document Availability

10. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

11. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

12. User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Issued: July 18, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–15715 Filed 7–24–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0624]

RIN 1625–AA00

Safety Zone; Straits of Mackinac Swim Event, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Straits of Mackinac within 250-yards of the Mackinac Bridge. The safety zone is needed to protect 400 swimmers participating in a swim across the Mackinac Straits from risks associated with the boating public. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie.

[8] *See Automatic Authorization for Holding Certain Positions that Require Commission Approval Under Section 305(b) of the Federal Power Act,* Order No. 446, 34 FERC 61,168 at 30,129–30,131 (1986).

[9] 18 CFR 45.2(b)(2).

[10] *See* Public Law 106–102, sec. 737, 113 Stat. 1338, 1479 (1999) (known as the Gramm-Leach-Bliley Act).

[11] 18 CFR 45.2(b)(2).

[12] Order No. 856, 166 FERC ¶ 61,119 at P 6; *see also* 16 U.S.C. 825d(b)(2).

[13] El Paso Request for Rehearing at 4–5.

DATES: This rule is effective from 7 a.m. through 11 a.m. on August 11, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0624 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Sean Murphy, Waterways Management, Sector Sault Sainte Marie, U.S. Coast Guard; telephone 906–635–3223, email *Sean.V.Murphy@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the final details of the specific marine event and safety zone distance were not finalized within a sufficient time to allow for notice and a subsequent comment period before the commencement of the planned marine event. Delaying this rule to allow for a notice and comment period would be impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect the 400 swimmers participating in this swim event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because prompt action is needed to protect the 400 swimmers participating in this event on August 11, 2019.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sault Sainte Marie (COTP) has determined that potential hazards associated with 400 swimmers swimming across the Straits of Mackinac in a swim event will be a safety concern for anyone within 250 yards of the Mackinac Bridge. This rule is needed to protect event participants and support vessels during the event.

IV. Discussion of the Rule

This rule establishes a safety zone from 7 a.m. until 11 a.m. on August 11, 2019. The safety zone will cover all navigable waters within 250 yards of the Mackinac Bridge. The duration of the zone is intended to protect event swimmers and support vessels during the marine event. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, duration, and location of the safety zone. Vessel traffic may request permission to transit the zone from the designated representative of the Captain of the Port, who may escort the vessel across the Safety Zone when there is no risk to the event participants. The field of swimmers will not spread across the entirety of the waterway; thus, there will be opportunity for a designated representative of the Captain of the Port to escort vessels requesting to transit the zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a 250 yard safety zone around the Mackinac Bridge. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures 5090.1. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0624 to read as follows:

§ 165.T09–0624 Safety Zone; Straits of Mackinac Swim Event, MI.

(a) *Location.* The following area is a safety zone: All navigable waters, from top to bottom, within 250 yards of the Mackinac Bridge in the Straits of Mackinac.

(b) *Effective and enforcement period.* This section will be enforced from 7 a.m. to 11 a.m. on August 11, 2019.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, hail the COTP's representative on an appropriate VHF channel. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

Dated: July 22, 2019.

P.S. Nelson,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2019–15834 Filed 7–24–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0625]

Safety Zones; Recurring Safety Zones in Captain of the Port Sault Sainte Marie Zone for Events Beginning in Late July 2019

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce established safety zones for maritime events starting in late July 2019 to provide for the safety of life on navigable waterways. Our regulation for safety zones within the Captain of the Port Sault Sainte Marie Zone identifies the regulated area for these safety zones. During the enforcement periods, vessels must stay out of the established safety zone and may only enter with permission from the designated representative of the Captain of the Port Sault Sainte Marie.

DATES: The regulations in 33 CFR 165.918 will be enforced for the safety zones identified in Table 1 of the **SUPPLEMENTARY INFORMATION** section of this document for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication, call or email LT Sean Murphy, Waterways Management, Coast Guard Sector Sault Sainte Marie, U.S. Coast Guard; telephone 906–635–3223, email *Sean.V.Murphy@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones in 33 CFR 165.918 as per the time, dates, and locations in Table 1.

TABLE 1

[Datum NAD 1983]

Event	Location	Event date
(1) Charlevoix Venetian Festival Friday Night Fireworks; Charlevoix, MI.	All U.S. navigable waters of Lake Charlevoix, in the vicinity of Depot Beach, within the arc of a circle with an approximate 1200-foot radius from the fireworks launch site located on a barge in position 45°19′08″ N, 085°14′18″ W.	July 26, 2019 from 9:30 p.m. to 11 p.m.
(2) Charlevoix Venetian Saturday Night Fireworks; Charlevoix, MI.	All U.S. navigable waters of Round Lake within the arc of a circle with an approximate 250-foot radius from the fireworks launch site located on a barge in position 45°19′03″ N, 085°15′18″ W.	July 27, 2019 from 9:30 p.m. to 11 p.m.
(3) Elk Rapids Harbor Days Fireworks; Elk Rapids, MI.	All U.S. navigable waters within the arc of a circle with an approximate 350-foot radius from the fireworks launch site located on a barge in position 44°54′6.95″ N, 85°25′3.11″ W.	August 3, 2019 from 9:30 p.m. to 10:30 p.m.
(4) Nautical City Fireworks; Rogers City.	All U.S. navigable waters within the arc of a circle with an approximate 560-foot radius from the fireworks launch site located near Harbor View Road in position 45°25′04.72″ N, 83°47′51.21″ W.	August 4, 2019 from 9:30 p.m. to 10:30 p.m. Rain date August 11, 2019 from 9:30 p.m. to 10:30 p.m.

This action is being taken to provide for the safety of life on navigable waterways during the fireworks displays. The regulations for safety zones within the Captain of the Port Sault Sainte Marie Zone, § 165.918, apply for these fireworks displays.

This notice of enforcement is issued under authority of 33 CFR 165.918 and 5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Sault Sainte Marie determines that the safety zone need not be enforced for the full duration stated in this notice of enforcement he or she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: July 22, 2019.

P.S. Nelson,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2019–15789 Filed 7–24–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2019–0593]

Safety Zone; Recurring Events in Captain of the Port Duluth Zone—Superior Man Triathlon

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone regulation for the Superior Man Triathlon event in Duluth, MN from 5:30 a.m. through 8:30 a.m. on August 10, 2019. This action is necessary to protect participants and spectators during the event. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his or her designated on-scene representative.

DATES: The regulations in Table 1 to 33 CFR 165.94, item (11), will be enforced from 5:30 a.m. through 8:30 a.m. on August 10, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email LT Abbie Lyons, Chief of Waterways Management, Coast Guard; telephone (218) 725–3818, email *DuluthWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone regulation for the annual Superior Man Triathlon event in 33 CFR 165.943, Table 1, item (11), from 5:30 a.m. through 8:30 a.m. on August 10, 2019 on all waters of the Duluth Harbor Basin, Northern Section in Duluth, MN within an imaginary line created by the following coordinates: 46°46′36″ N, 092°06′06″ W, moving southeast to 46°46′32″ N, 092°06′01″ W, then moving northeast to 46°46′45″ N, 092°05′45″ W, then moving northwest to 46°46′49″ N, 092°05′49″ W, and finally returning to the starting position.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his or her designated on-scene representative. The Captain of the Port Duluth or his or her on-scene representative may be contacted via VHF Channel 16.

This document is issued under authority of 33 CFR 165.943 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 of the enforcement of this safety zone via Broadcast Notice to Mariners.

Dated: July 22, 2019.

F.M. Smith,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2019–15798 Filed 7–24–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2017–0758; FRL–9996–92–Region 4]

Air Plan Approval; Kentucky: Jefferson County Definitions and Federally Enforceable District Origin Operating Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted under cover letters dated December 21, 2016, and August 25, 2017, by the Commonwealth of Kentucky, through the Energy and Environment Cabinet (Cabinet). The SIP revisions were submitted by the Cabinet on behalf of the Louisville Metro Air Pollution Control District (LMAPCD or District) and make amendments to Jefferson County's regulations regarding definitions and the federally enforceable district origin operating permit (FEDOOP) program. EPA is approving the revisions modifying these regulations because the Agency believes

they are consistent with the Clean Air Act (CAA or Act).

DATES: This rule will be effective August 26, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2017–0758. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: D. Brad Akers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Mr. Akers can be reached via telephone at 404–562–9089 or via electronic mail at *akers.brad@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA is approving changes to the Jefferson County portion of the Kentucky SIP that were provided to EPA through letters dated December 21, 2016 and August 25, 2017.[1] [2] Both submittals make changes to Regulation 1.02,—''Definitions,'' to incorporate various new definitions and revise existing definitions. The August 25, 2017, submittal also makes changes to Regulation 2.17,—''Federally Enforceable District Origin Operating Permits [FEDOOP],'' to make clarifying and administrative edits to this portion of the minor source operating permit program. The changes addressed in this final rulemaking also correct typographical errors, make minor administrative and clarifying edits, and recodify sections of the existing rules.

Specifically, the August 25, 2017, SIP revision includes several changes to Regulation 1.02,—''Definitions,'' as follows: (1) Adds a definition for ''administrative permit revision''; (2) adds a definition for ''emissions unit'' or ''facility''; (3) adds a definition for ''insignificant activity''; (4) adds a definition for ''minor permit revision''; (5) adds a definition for ''minor source''; (6) adds a definition for ''regulated air pollutant''; (7) adds a definition for ''responsible official''; (8) adds a definition for ''significant permit revision''; (9) adds a definition for ''trivial activities''; (10) adds a definition for ''twelve month rolling period'' or ''12-month rolling period''; and (11) makes other clarifying and administrative edits to definitions throughout the Section, including renumbering. The December 21, 2016, submittal [3] makes further edits to Regulation 1.02 to incorporate changes to the definition of volatile organic compounds (VOC), consistent with Federal regulations, and to make other administrative edits to definitions throughout the Section.

The August 25, 2017, SIP revision also modifies Regulation 2.17 to include provisions for Section 4,—''Permit Applications,'' to describe the required content of FEDOOP applications, including the treatment of ''insignificant activities'' and ''trivial activities.'' The District's changes at Regulation 2.17, Section 4—as applicable to sources subject to FEDOOP requirements—are consistent with EPA's permit application requirements for title V sources. Furthermore, Regulation 2.17 is changed at Section 3 to clarify that a set 5-year term applies to FEDOOPs prior to a required renewal. There are no Federal term limit requirements applicable to these minor source operating permits, though EPA notes the 5-year time period is consistent with Federal title V requirements.

See EPA's May 20, 2019, (84 FR 22771) proposed rule (NPRM) for further detail on these changes and EPA's rationale for approving them. EPA received no adverse comments on the NPRM. Therefore, in this action, EPA is approving these SIP revisions that make changes to Jefferson County's definitions and FEDOOP regulations because they are consistent with the CAA.

II. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Jefferson County's Regulation 1.02,—''Definitions,'' version 14, State effective September 21, 2016,[4] which makes various changes to applicable definitions, and Regulation 2.17,—''Federally Enforceable District Origin Operating Permits,'' version 4, effective May 15, 2013, which adds provisions describing permit application content for these types of permits. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[5]

[1] EPA notes that the Agency received the SIP revision dated August 25, 2017 on August 29, 2017.

[2] In 2003, the City of Louisville and Jefferson County governments merged and the ''Jefferson County Air Pollution Control District'' was renamed the ''Louisville Metro Air Pollution Control District.'' However, each of the regulations in the Jefferson County portion of the Kentucky SIP still has the subheading ''Air Pollution Control District of Jefferson County.'' Thus, to be consistent with the terminology used in the SIP, we refer throughout this notice to regulations contained in the Jefferson County portion of the Kentucky SIP as the ''Jefferson County'' regulations.

[3] The December 21, 2016, SIP revision includes version 14 of Regulation 1.02, but was submitted before version 13 was submitted. Regulation 1.02, version 13 was submitted on August 25, 2017. The December 21, 2016, submittal includes two separate redline/strikeout documents for Regulation 1.02. The first document, beginning on page 13 of the PDF submittal, shows all changes made in versions 11, 12, 13, and 14 of that rule. The second document, beginning on page 27 of the pdf submittal, shows only those changes made in version 14. EPA previously approved versions 11 and 12. *See* 81 FR 87815 (December 6, 2016); 82 FR 35101 (July 28, 2017). Accordingly, we are only approving changes included in versions 13 and 14 of Regulation 1.02—as submitted on August 25, 2017, and December 21, 2016, respectively—in this action.

[4] The District approved version 13 of Regulation 1.02 on July 2, 2013, and version 14 on September 21, 2016. The Commonwealth forwarded the regulations to EPA in the opposite order. Although the most recent submittal by the Commonwealth transmits version 13, EPA understands the Commonwealth's intent is to incorporate version 14 of the regulation into the SIP (thereby incorporating changes in both versions 13 and 14). For that reason, EPA is incorporating by reference Regulation 1.02 as of version 14's State-effective date, September 21, 2016.

[5] *See* 62 FR 27968 (May 22, 1997).

III. Final Action

EPA is approving Kentucky's December 21, 2016, and August 25, 2017, SIP revisions. Specifically, EPA is approving these SIP revisions to Jefferson County's Regulations 1.02 and 2.17. The changes at Regulation 1.02 add or modify definitions relating to the permitting program, modify the definition of VOC, and make other clarifying and administrative edits throughout the rule. The changes to Regulation 2.17 specify required content of permit applications and set a term limit and renewal period for FEDOOPs, consistent with similar practices for the Federal title V permitting program. As discussed in further detail in EPA's May 20, 2019, (84 FR 22771) NPRM, the Agency is approving these SIP revisions because the Agency has determined that they are consistent with the CAA and will not interfere with attainment or maintenance of any NAAQS, reasonable further progress, or any other applicable requirement.

IV. Statutory and Executive Order Reviews

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

- Are 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);
- Are not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are 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.*);
- Do 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);
- Do not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Do not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 23, 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 Preference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 11, 2019.

Mary S. Walker,

Regional Administrator, Region 4.

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 S—Kentucky

■ 2. Section 52.920(c), Table 2, is amended by:

■ a. Under the heading ''Reg 1—General Provisions,'' revising the entry for ''1.02''; and

■ b. Under the heading ''Reg 2—Permit Requirements,'' revising the entry for ''2.17''.

The revisions read as follows:

§ 52.920 Identification of plan.

* * * * *

(c) * * *

TABLE 2—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY

Reg	Title/subject	EPA approval date	**Federal Register** notice	District effective date	Explanation
Reg 1—General Provisions					

TABLE 2—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY—Continued

Reg	Title/subject	EPA approval date	Federal Register notice	District effective date	Explanation
*	*	*	*	*	*
1.02	Definitions	7/25/2019	[Insert citation of publication]	09/21/2016	
*	*	*	*	*	*
Reg 2—Permit Requirements					
*	*	*	*	*	*
2.17	Federally Enforceable District Origin Operating Permits.	7/25/2019	[Insert citation of publication]	5/15/2013	
*	*	*	*	*	*

* * * * *

[FR Doc. 2019–15762 Filed 7–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2019–0063; FRL–9996–96–Region 8]

Approval and Promulgation of Air Quality Implementation Plans; State of Utah; Revisions to Nonattainment Permitting Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve State Implementation Plan (SIP) revisions submitted by the State of Utah on March 27, 2014, and August 7, 2018. The submittals revise the portions of the Utah Administrative Code (UAC) that pertain to the issuance of Utah air quality permits for major sources in nonattainment areas. This action is being taken under the Clean Air Act (CAA or Act).

DATES: This final rule is effective on August 26, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2019–0063. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Kevin Leone, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–QP, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6227, *leone.kevin@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' means the EPA.

I. Background

The EPA is taking final action to fully approve two revisions submitted by the State of Utah on March 27, 2014, and August 7, 2018. The EPA published a proposed rulemaking for these submittals on June 5, 2019 (84 FR 26049). As stated in our proposed rulemaking, Utah submitted revisions to their nonattainment New Source Review (NNSR) permitting program on August 20, 2013. The August 20, 2013 submittal added volatile organic compounds (VOCs) as a fine particulate matter ($PM_{2.5}$) precursor to the NNSR program; however, the submittal did not establish a significant emissions rate (SER) for VOC to determine when a modification at an existing major source would be a major modification subject to NNSR review. On March 27, 2014, Utah submitted a revision to address the omission and establish the VOC SER. The EPA determined that Utah needed to submit further revisions to address the remaining deficiencies in the NNSR permitting program in order for the EPA to fully approve Utah's August 20, 2013 submittal. These deficiencies are outlined in our proposed rulemaking.

On September 30, 2016 Utah submitted to the EPA a letter committing to address the remaining deficiencies in the State's nonattainment permitting program in R307–403 that were not addressed in the August 20, 2013 submittal (see docket). Based on the September 30, 2016 commitment letter, on February 3, 2017 (82 FR 918), the EPA conditionally approved Utah's August 20, 2013 submittal. On October 5, 2017 (82 FR 46417), we approved a June 29, 2017 submittal that, among other things, addressed the deficiency in R307–403–6 identified in our conditional approval.

On August 7, 2018, Utah submitted further revisions to address the remaining deficiencies in their NNSR program. This submittal also provides a technical demonstration for exempting ammonia as a $PM_{2.5}$ precursor in the Logan, Utah-Idaho $PM_{2.5}$ nonattainment areas and a technical basis for setting an ammonia SER of 70 tons per year in the Salt Lake City and Provo $PM_{2.5}$ nonattainment areas.

We provided a detailed explanation of the basis for our proposed approval in our June 5, 2019, rulemaking, which will not be restated here. See 84 FR 26049. We invited comment on all aspects of our proposal and provided a 30-day comment period. The comment period ended on July 5, 2019.

II. Response to Comments

We received no comments during the public comment period.

III. Final Action

As outlined in our proposed rulemaking, the EPA is taking final action to approve the addition of new and revised rules and renumbering to rules R307–101 and R307–403 that were submitted by Utah on March 27, 2014 and August 7, 2018. This final action, in tandem with our October 5, 2017 approval of R307–403–6, converts the

February 3, 2017 conditional approval to a full approval.

Specifically, we are taking final action to approve the following revisions: R307–101 (General Requirements)—R307–101–2 *(Definitions);* R307–403 (Permits: New and Modified Sources in Nonattainment Areas and Maintenance Areas)—R307–403–1 *(Purpose and Definitions):* R307–403–1(1)–(3), R307–403–1(4)(b), R307–403–1(4)(c); R307–403–2 *(Applicability):* R307–403–2(1), R307–403–2(6)(d); R307–403–2(10); R307–403–2(10)(a)–(c); R307–403–2(13); R307–403–3 *(Review of Major Sources of Air Quality Impact):* R307–403–3, R307–403–3(1), R307–403–3(3), R307–403–3(3)(a), R307–403–3(c), R307–403–3(d), R307–403–3(3)(e); R307–403–4 *(Offsets: General Requirements):* R307–403–4(1), R307–403–4(2), R307–403–4(3), R307–403–4(4); R307–403–5 *(Offsets: Particulate Matter Nonattainment Areas):* R307–403–5(1), R307–403–5(1)(a), R307–403–5(1)(b), R307–403–5(1)(c), R307–403–5(1)(d), R307–403–5(1)(e), R307–403–5(2), R307–403–5(2)(a), R307–403–5(2)(b), R307–403–5(2)(b)(i)–(iii), R307–403–5(2)(d), R307–403–5(4)(a), R307–403–5(4)(b), R307–403–5(4)(d), R307–403–5(e), R307–403–5(f); R307–403–7 *(Offsets: Baseline);* and R307–403–9 *(Construction in Stages).*

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the State of Utah's revisions to its State Implementation Plan as described in section III. of this preamble. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the 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, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the 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 September 23, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: July 19, 2019.

Gregory Sopkin,

Regional Administrator, Region 8.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart TT—Utah

■ 2. Section 52.2320(c) is amended in the table:

[1] 62 FR 27968 (May 22, 1997).

■ a. Under the centered heading ''R307–101. General Requirements,'' by revising the entry for ''R307–101–2.''
■ b. Under the centered heading ''R307–403. Permits: New and Modified Sources in Nonattainment Areas and Maintenance Areas'':
■ i. By revising the entries for ''R307–403–1'' and ''R307–403–2;''
■ ii. By adding in numerical order entries for ''R307–403–3;'' ''R307–403–4;'' and ''R307–403–5;''
■ iii. By revising the entry for ''R307–403–6;''
■ iv. By adding in numerical order entries for ''R307–403–7'' and ''R307–403–9;'' and
■ v. By revising the entries for ''R307–403–10'' and ''R307–403–11.''

The revisions and additions read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

Rule No.	Rule title	State effective date	Final rule citation, date	Comments
R307–101. General Requirements				
*	*	*	*	*
R307–101–2	Definitions	08/02/2018	[Insert **Federal Register** citation], 7/25/2019..	
*	*	*	*	*
R307–403. Permits: New and Modified Sources in Nonattainment Areas and Maintenance Areas				
*	*	*	*	*
R307–403–1	Purpose and Definitions	08/02/2018 12/04/2013	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–2	Applicability	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–3	Review of Major Sources of Air Quality Impact.	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–4	Offsets: General Requirements	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–5	Offsets: Particulate Matter Nonattainment Areas.	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–6	Offsets: Ozone Nonattainment Areas.	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–7	Offsets: Baseline	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–9	Construction in Stages	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–10	Analysis of Alternatives	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
R307–403–11	Actual PALS	08/02/2018	[Insert **Federal Register** citation], 7/25/2019.	
*	*	*	*	*

* * * * *

[FR Doc. 2019–15795 Filed 7–24–19; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2019–0003; Internal Agency Docket No. FEMA–8589]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase

Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notification withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region V				
Illinois:				
Addison, Village of, DuPage County	170198	July 23, 1973, Emerg; March 15, 1979, Reg; August 1, 2019, Susp.	Aug. 1, 2019	Aug. 1, 2019.
Bartlett, Village of, Cook, DuPage and Kane Counties.	170059	October 15, 1974, Emerg; June 15, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Bensenville, Village of, Cook and DuPage Counties.	170200	May 22, 1974, Emerg; February 4, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Bloomingdale, Village of, DuPage County.	170201	June 6, 1974, Emerg; April 15, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Carol Stream, Village of, DuPage County.	170202	September 4, 1973, Emerg; January 6, 1982, Reg; August 1, 2019, Susp.	.....do	Do.
Chicago, City of, Cook and DuPage Counties.	170074	August 23, 1974, Emerg; June 1, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Darien, City of, DuPage County	170750	September 6, 1974, Emerg; February 1, 1980, Reg; August 1, 2019, Susp.	.....do	Do.
Elk Grove Village, Village of, Cook and DuPage Counties.	170088	November 3, 1972, Emerg; June 15, 1979, Reg; August 1, 2019, Susp.	.....do	Do.
Hanover Park, Village of, Cook and DuPage Counties.	170099	April 19, 1973, Emerg; November 15, 1978, Reg; August 1, 2019, Susp.	.....do	Do.
Hinsdale, Village of, Cook and DuPage Counties.	170105	April 22, 1975, Emerg; January 16, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Itasca, Village of, DuPage County	170210	May 29, 1973, Emerg; November 2, 1977, Reg; August 1, 2019, Susp.	.....do	Do.
Lisle, Village of, DuPage County	170211	July 6, 1973, Emerg; September 17, 1980, Reg; August 1, 2019, Susp.	.....do	Do.
Lombard, Village of, DuPage County	170212	December 29, 1972, Emerg; October 17, 1978, Reg; August 1, 2019, Susp.	.....do	Do.
Oak Brook, Village of, Cook and DuPage Counties.	170214	January 13, 1975, Emerg; February 18, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Oakbrook Terrace, City of, DuPage County.	170215	April 15, 1975, Emerg; February 18, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Roselle, Village of, Cook and DuPage Counties.	170216	March 2, 1973, Emerg; May 19, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Schaumburg, Village of, Cook and DuPage Counties.	170158	October 13, 1972, Emerg; February 15, 1979, Reg; August 1, 2019, Susp.	.....do	Do.
Villa Park, Village of, DuPage County ..	170217	April 23, 1974, Emerg; February 4, 1981, Reg; August 1, 2019, Susp.	.....do	Do.
Wood Dale, City of, DuPage County	170224	February 2, 1973, Emerg; September 30, 1977, Reg; August 1, 2019, Susp.	.....do	Do.
Region VII				
Nebraska:				
Aurora, City of, Hamilton County	310105	December 23, 1974, Emerg; August 16, 1988, Reg; August 1, 2019, Susp.	.....do	Do.
Hamilton County, Unincorporated Areas	310441	N/A, Emerg; June 21, 1993, Reg; August 1, 2019, Susp.	.....do	Do.
Henderson, City of, York County	310378	July 7, 1975, Emerg; September 4, 1986, Reg; August 1, 2019, Susp.	.....do	Do.
McCool Junction, Village of, York County.	310236	June 4, 1975, Emerg; September 4, 1987, Reg; August 1, 2019, Susp.	.....do	Do.
Waco, Village of, York County	310331	March 16, 2011, Emerg; August 31, 2011, Reg; August 1, 2019, Susp.	.....do	Do.
York County, Unincorporated Areas	310486	April 16, 1980, Emerg; September 1, 1986, Reg; August 1, 2019, Susp.	.....do	Do.
Region X				
Alaska: Sitka, City and Borough of	020006	November 8, 1974, Emerg; June 1, 1982, Reg; August 1, 2019, Susp.	.....do	Do.

.....do, Do. = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: July 15, 2019.

Katherine B. Fox,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2019–15765 Filed 7–24–19; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 180625576–8999–02]

RIN 0648–BI94

Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; 2019–2020 Biennial Specifications and Management Measures; Inseason Adjustments

Correction

In rule document 2019–11610, appearing on pages 25708 through 25720, in the issue of Tuesday, June 4, 2019, Table 2 (South) and Table 3 (South) are corrected to read as below:

Part 660, Subpart E [Corrected]

■ 1. On page 25716, Table 2 (South) is republished as follows:

BILLING CODE 1301–00–D

Table 2 (South) to Part 660, Subpart E -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Limited Entry Fixed Gear South of 40°10' N. lat.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table — 06/01/2019

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[1/]:						
1	40°10' N. lat. - 34°27' N. lat.	40 fm line[1/] - 125 fm line[1/]					
2	South of 34°27' N. lat.	75 fm line[1/] - 150 fm line[1/] (also applies around islands)					
	See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).						
	State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
3	**Minor Slope rockfish[2/] & Darkblotched rockfish**	40,000 lb/ 2 months, of which no more than 1,375 lb may be blackgill rockfish		40,000 lb/ 2 months, of which no more than 4,000 lb may be blackgill rockfish			
4	**Splitnose rockfish**	40,000 lb/ 2 months					
5	**Sablefish**						
6	40°10' N. lat. - 36°00' N. lat.	1,300 lb/week, not to exceed 3,900 lb/ 2 months					
7	South of 36°00' N. lat.	2,000 lb/ week					
8	**Longspine thornyhead**	10,000 lb/ 2 months					
9	**Shortspine thornyhead**						
10	40°10' N. lat. - 34°27' N. lat.	2,000 lb/ 2 months				2,500 lb/ 2 months	
11	South of 34°27' N. lat.	3,000 lb/ 2 months					
12 13 14 15 16 17	**Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish[3/]**	5,000 lb/ month South of 42° N. lat., when fishing for "other flatfish," vessels using hook-and-line gear with no more than 12 hooks per line, using hooks no larger than "Number 2" hooks, which measure 0.44 in (11 mm) point to shank, and up to two 1 lb (0.45 kg) weights per line, are not subject to the RCAs.					
18	**Whiting**	10,000 lb/ trip					
19	**Minor Shelf Rockfish[2/], Shortbelly rockfish, Widow rockfish (including Chilipepper between 40°10' - 34°27' N. lat.)**						
20	40°10' N. lat. - 34°27' N. lat.	Minor shelf rockfish, shortbelly, widow rockfish, & chilipepper: 2,500 lb/ 2 months, of which no more than 500 lb may be any species other than chilipepper.					
21	South of 34°27' N. lat.	4,000 lb/ 2 months	CLOSED	4,000 lb/ 2 months			
22	**Chilipepper**						
23	40°10' N. lat. - 34°27' N. lat.	Chilipepper included under minor shelf rockfish, shortbelly and widow rockfish limits - - See above					
24	South of 34°27' N. lat.	2,000 lb/ 2 months, this opportunity only available seaward of the non-trawl RCA					
25	**Canary rockfish**						
26	40°10' N. lat. - 34°27' N. lat.	300 lb/ 2 months					
27	South of 34°27' N. lat.	300 lb/ 2 months	CLOSED	300 lb/ 2 months			
28	**Yelloweye rockfish**	CLOSED					
29	**Cowcod**	CLOSED					
30	**Bronzespotted rockfish**	CLOSED					
31	**Bocaccio**						
32	40°10' N. lat. - 34°27' N. lat.	1,000 lb/ 2 months					
33	South of 34°27' N. lat.	1,500 lb/ 2 months	CLOSED	1,500 lb/ 2 months			
34	**Minor Nearshore Rockfish, California Black rockfish, & Oregon Black/Blue/Deacon rockfish**						
35	Shallow nearshore[4/]	1,200 lb/ 2 months	CLOSED	1,200 lb/ 2 months			
36	Deeper nearshore[5/]	1,000 lb/ 2 months	CLOSED	1,200 lb/ 2 months			
37	**California Scorpionfish**	1,500 lb/ 2 months	CLOSED	1,500 lb/ 2 months			
38	**Lingcod[6/]**	200 lb/ 2 months	CLOSED	1,200 lb/ 2 months			
39	**Pacific cod**	1,000 lb/ 2 months					
40	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2 months		100,000 lb/ 2 months	
41	**Longnose skate**	Unlimited					
42	**Other Fish[7/] & Cabezon in California**	Unlimited					
43	**Big Skate**	Unlimited					

TABLE 2 (South)

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ POP is included in the trip limits for Minor Slope Rockfish. Blackgill rockfish have a species specific trip sub-limit within the Minor Slope Rockfish cumulative limit. Yellowtail rockfish are included in the trip limits for Minor Shelf Rockfish. Bronzespotted rockfish have a species specific trip limit.

3/ "Other Flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*1*).

5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*2*).

6/ The commercial mimimum size limit for lingcod is 24 inches (61 cm) total length South of 42° N. lat.

7/ "Other Fish" are defined at § 660.11 and include kelp greenling off California and leopard shark.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

Part 660, Subpart F [Corrected]

■ 2. On pages 25719–25720, Table 3 (South) is republished as follows:

Table 3 (South) to Part 660, Subpart F -- Non-Trawl Rockfish Conservation Areas and Trip Limits for Open Access Gears South of 40°10' N. lat.

Other limits and requirements apply -- Read §§660.10 through 660.399 before using this table — 06/01/2019

TABLE 3 (South)

		JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
	Rockfish Conservation Area (RCA)[1/]:						
1	40°10' N. lat. - 34°27' N. lat.	40 fm line[1/] - 125 fm line[1/]					
2	South of 34°27' N. lat.	75 fm line[1/] - 150 fm line[1/](also applies around islands)					
	See §§660.60 and 660.230 for additional gear, trip limit and conservation area requirements and restrictions. See §§660.70-660.74 and §§660.76-660.79 for conservation area descriptions and coordinates (including RCAs, YRCAs, CCAs, Farallon Islands, Cordell Banks, and EFHCAs).						
	State trip limits and seasons may be more restrictive than Federal trip limits or seasons, particularly in waters off Oregon and California.						
3	**Minor Slope Rockfish[2/] & Darkblotched rockfish**	10,000 lb/ 2 months, of which no more than 475 lb may be blackgill rockfish		10,000 lb/ 2 months, of which no more than 800 lb may be blackgill rockfish			
4	**Splitnose rockfish**	200 lb/ month					
5	**Sablefish**						
6	40°10' N. lat. - 36°00' N. lat.	300 lb/ day or one landing per week up to 1,200 lb, not to exceed 2,400 lb/ 2 months					
7	South of 36°00' N. lat.	300 lb/ day, or one landing per week of up to 1,600 lb, not to exceed 3,200 lb/ 2 months					
8	**Shortpine thornyheads and longspine thornyheads**						
9	40°10' N. lat. - 34°27' N. lat.	CLOSED					
10	South of 34°27' N. lat.	50 lb/ day, no more than 1,000 lb/ 2 months					
11 12 13 14 15 16	**Dover sole, arrowtooth flounder, petrale sole, English sole, starry flounder, Other Flatfish[3/]**	3,000 lb/ month, no more than 300 lb of which may be species other than Pacific sanddabs. South of 42° N. lat., when fishing for "other flatfish," vessels using hook-and-line gear with no more than 12 hooks per line, using hooks no larger than "Number 2" hooks, which measure 0.44 in (11 mm) point to shank, and up to two 1 lb (0.45 kg) weights per line are not subject to the RCAs.					
17	**Whiting**	300 lb/ month					
18	**Minor Shelf Rockfish[2/], Shortbelly, Widow rockfish and Chilipepper**						
19	40°10' N. lat. - 34°27' N. lat.	400 lb/ 2 months	CLOSED	400 lb/ 2 months			
20	South of 34°27' N. lat.	1,500 lb/ 2 months		1,500 lb/ 2 months			
21	**Canary rockfish**	300 lb/ 2 months	CLOSED	300 lb/ 2 months			
22	**Yelloweye rockfish**	CLOSED					
23	**Cowcod**	CLOSED					
24	**Bronzespotted rockfish**	CLOSED					
25	**Bocaccio**	500 lb/ 2 months	CLOSED	500 lb/ 2 months			
26	**Minor Nearshore Rockfish, California Black rockfish, & Oregon Black/Blue/Deacon rockfish**						
27	Shallow nearshore[4/]	1,200 lb/ 2 months	CLOSED	1,200 lb/ 2 months			
28	Deeper nearshore[5/]	1,000 lb/ 2 months	CLOSED	1,200 lb/ 2 months			
29	**California scorpionfish**	1,500 lb/ 2 months	CLOSED	1,500 lb/ 2 months			
30	**Lingcod[6/]**	300 lb/ month	CLOSED	500 lb/ month			
31	**Pacific cod**	1,000 lb/ 2 months					
32	**Spiny dogfish**	200,000 lb/ 2 months		150,000 lb/ 2 months	100,000 lb/ 2 months		
33	**Longnose skate**	Unlimited					
34	**Big skate**	Unlimited					
35	**Other Fish[7/] & Cabezon in California**	Unlimited					

Table 3 (South). Continued

TABLE 3 (South) cont'd

			JAN-FEB	MAR-APR	MAY-JUN	JUL-AUG	SEP-OCT	NOV-DEC
36	**RIDGEBACK PRAWN AND, SOUTH OF 38°57.50' N. LAT., CA HALIBUT AND SEA CUCUMBER NON-GROUNDFISH TRAWL**							
37	**NON-GROUNDFISH TRAWL Rockfish Conservation Area (RCA) for CA Halibut, Sea Cucumber & Ridgeback Prawn:**							
38		*40° 10' N. lat. - 38° 00' N. lat.*	*100 fm line 1/ - 200 fm line 1/*	*100 fm line 1/ - 150 fm line 1/*				*100 fm line 1/ - 200 fm line 1/*
39		*38° 00' N. lat. - 34° 27' N. lat.*	*100 fm line 1/ - 150 fm line 1/*					
40		*South of 34° 27' N. lat.*	*100 fm line 1/ - 150 fm line 1/ along the mainland coast; shoreline - 150 fm line 1/ around islands*					
41			Groundfish: 300 lb/trip. Species-specific limits described in the table above also apply and are counted toward the 300 lb groundfish per trip limit. The amount of groundfish landed may not exceed the amount of the target species landed, except that the amount of spiny dogfish landed may exceed the amount of target species landed. Spiny dogfish are limited by the 300 lb/trip overall groundfish limit. The daily trip limits for sablefish coastwide and thornyheads south of Pt. Conception and the overall groundfish "per trip" limit may not be multiplied by the number of days of the trip. Vessels participating in the California halibut fishery south of 38°57.50' N. lat. are allowed to (1) land up to 100 lb/day of groundfish without the ratio requirement, provided that at least one California halibut is landed and (2) land up to 3,000 lb/month of flatfish, no more than 300 lb of which may be species other than Pacific sanddabs, sand sole, starry flounder, rock sole, curlfin sole, or California scorpionfish (California scorpionfish is also subject to the trip limits and closures in line 29).					
42	**PINK SHRIMP NON-GROUNDFISH TRAWL GEAR** *(not subject to RCAs)*							
43		South	Effective April 1 - October 31: Groundfish: 500 lb/day, multiplied by the number of days of the trip, not to exceed 1,500 lb/trip. The following sublimits also apply and are counted toward the overall 500 lb/day and 1,500 lb/trip groundfish limits: lingcod 300 lb/ month (minimum 24 inch size limit); sablefish 2,000 lb/ month; canary rockfish, thornyheads and yelloweye rockfish are PROHIBITED. All other groundfish species taken are managed under the overall 500 lb/day and 1,500 lb/trip groundfish limits. Landings of all groundfish species count toward the per day, per trip or other species-specific sublimits described here and the species-specific limits described in the table above do not apply. The amount of groundfish landed may not exceed the amount of pink shrimp landed.					

1/ The Rockfish Conservation Area is an area closed to fishing by particular gear types, bounded by lines specifically defined by latitude and longitude coordinates set out at §§ 660.71-660.74. This RCA is not defined by depth contours (with the exception of the 20-fm depth contour boundary south of 42° N. lat.), and the boundary lines that define the RCA may close areas that are deeper or shallower than the depth contour. Vessels that are subject to RCA restrictions may not fish in the RCA, or operate in the RCA for any purpose other than transiting.

2/ POP is included in the trip limits for minor slope rockfish. Blackgill rockfish have a species specific trip sub-limit within the minor slope rockfish cumulative limits. Yellowtail rockfish is included in the trip limits for minor shelf rockfish. Bronzespotted rockfish have a species specific trip limit.

3/ "Other flatfish" are defined at § 660.11 and include butter sole, curlfin sole, flathead sole, Pacific sanddab, rex sole, rock sole, and sand sole.

4/ "Shallow Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*1*).

5/ "Deeper Nearshore" are defined at § 660.11 under "Groundfish" (7)(i)(B)(*2*).

6/ The commercial mimimum size limit for lingcod is 24 inches (61 cm) total length South of 42° N. lat.

7/ "Other fish" are defined at § 660.11 and includes kelp greenling off California and leopard shark.

To convert pounds to kilograms, divide by 2.20462, the number of pounds in one kilogram.

[FR Doc. C1–2019–11610 Filed 7–24–19; 8:45 am]

BILLING CODE 1301–00–C

Proposed Rules

Federal Register
Vol. 84, No. 143
Thursday, July 25, 2019

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0525; Product Identifier 2019–NM–076–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2006–11–11, which applies to all The Boeing Company Model 757 airplanes. AD 2006–11–11 requires incorporating a new revision to the Airworthiness Limitations section of the Instructions of Continued Airworthiness to mandate certain repetitive inspections for fatigue cracking of principal structural elements (PSEs). Since AD 2006–11–11 was issued, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 9, 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 Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0525.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0525; 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 is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Chandraduth Ramdoss, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites 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–2019–0525; Product Identifier 2019–NM–076–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

The FAA will post all comments received, without change, to *http://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this proposed AD.

Discussion

The FAA issued AD 2006–11–11, Amendment 39–14615 (71 FR 30278, May 26, 2006) (''AD 2006–11–11''), for all The Boeing Company Model 757 airplanes. AD 2006–11–11 requires incorporating a new revision to the Airworthiness Limitations section of the Instructions of Continued Airworthiness to mandate certain repetitive inspections for fatigue cracking of PSEs. AD 2006–11–11 resulted from a new revision to the Airworthiness Limitations Instructions (ALI). The FAA issued AD 2006–11–11 to address fatigue cracking of various PSEs; such fatigue cracking could adversely affect the structural integrity of these airplanes.

Actions Since AD 2006–11–11 Was Issued

Since AD 2006–11–11 was issued, the FAA has determined that new or more restrictive airworthiness limitations are necessary.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001–9, Revision October 2018. This service information describes procedures for airworthiness limitations for structural inspections, fuel tank systems, safe life limits, and certification maintenance requirements.

This proposed AD would also require the following service information, which the Director of the Federal Register approved for incorporation by reference as of June 30, 2006 (71 FR 30278, May 26, 2006).

- Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, ''Airworthiness Limitations and Certification Maintenance Requirements,'' Subsection B. of Boeing Document D622N001–9, Revision ''May 2003.''

• Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, ''Airworthiness Limitations and Certification Maintenance Requirements,'' Subsection B. of Boeing Document D622N001–9, Revision ''June 2005.''

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

The FAA is proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all requirements of AD 2006–11–11. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which would then terminate all of the retained requirements of AD 2006–11–11.

This proposed AD would require revisions to certain operator maintenance or inspection documents, as applicable, to include new actions (*e.g.,* inspections) and Critical Design Configuration Control Limitations (CDCCLs). Compliance with these actions and CDCCLs is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance according to paragraph (l) of this proposed AD.

Costs of Compliance

The FAA estimates that this proposed AD affects 561 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD.

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

Authority for This Rulemaking

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

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

This 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

The FAA has 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 that the proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

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 removing Airworthiness Directive (AD) 2006–11–11, Amendment 39–14615 (71 FR 30278, May 26, 2006), and adding the following new AD:

The Boeing Company: Docket No. FAA–2019–0525; Product Identifier 2019–NM–076–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by September 9, 2019.

(b) Affected ADs

This AD replaces AD 2006–11–11, Amendment 39–14615 (71 FR 30278, May 26, 2006) (''AD 2006–11–11'').

(c) Applicability

This AD applies to all The Boeing Company Model 757–200, –200PF, –200CB, and –300 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel; 53, Fuselage; 57, Wings.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking of various principal structural elements (PSEs); such fatigue cracking could adversely affect the structural integrity of these airplanes.

(f) Compliance

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

(g) Retained Revision to the Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2006–11–11 with no changes. Within 36 months after June 30, 2006 (the effective date of AD 2006–11–11), revise Section 9, ''Airworthiness Limitations and CMRs'' of the Boeing 757 Maintenance Planning Data (MPD) Document to incorporate Subsection B. of Boeing Document D622N001–9, Revision ''May

2003;'' or Revision ''June 2005,'' as applicable.

(h) Maintenance or Inspection Program Revision

Within 18 months after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001–9, Revision October 2018. The initial compliance time for doing the new or updated tasks is at the time specified in Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001–9, Revision October 2018, or within 18 months after the effective date of this AD, whichever occurs later. The compliance time for doing the unchanged tasks is at the time specified in Boeing 757 Maintenance Planning Data (MPD) Document, Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs), D622N001–9, Revision October 2018.

(i) No Alternative Actions, Intervals, or Critical Design Configuration Control Limitations (CDCCLs) for Paragraph (g) of This AD

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

(j) No Alternative Actions, Intervals, or CDCCLs for Paragraph (h) of This AD

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

(k) Terminating Action for Paragraph (g) of This AD

Accomplishing the revision required by paragraph (h) of this AD terminates the revision required by paragraph (g) of this AD.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles 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 (m)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-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.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously for AD 2001–20–12 and AD 2006–11–11 are approved as AMOCs for the corresponding provisions of this AD.

(m) Related Information

(1) For more information about this AD, contact Chandraduth Ramdoss, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5239; fax: 562–627–5210; email: *chandraduth.ramdoss@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; phone: 562–797–1717; internet: *https://www.myboeingfleet.com.* You may view this referenced 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 July 16, 2019.

Suzanne Masterson,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–15582 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 312

RIN 3084–AB20

Request for Public Comment on the Federal Trade Commission's Implementation of the Children's Online Privacy Protection Rule

AGENCY: Federal Trade Commission.

ACTION: Regulatory review; request for public comment.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') requests public comment on its implementation of the Children's Online Privacy Protection Act (''COPPA'' or ''the Act''), through the Children's Online Privacy Protection Rule (''COPPA Rule'' or ''the Rule'').

DATES: Written comments must be received on or before October 23, 2019. The Commission will hold a public workshop to review the COPPA Rule on October 7, 2019.

ADDRESSES: Interested parties may file a comment online or on paper by following the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''COPPA Rule Review, 16 CFR part 312, Project No. P195404,'' on your comment and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex 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.

The workshop will be held at the Constitution Center, 400 7th Street SW, Washington, DC. It is free and open to the public, and members of the public who wish to participate but cannot attend can view a live webcast at *ftc.gov*.

FOR FURTHER INFORMATION CONTACT: Kristin Cohen (202–326–2276) or Peder Magee (202–326–3538), Division of Privacy and Identity Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission typically reviews its Rules every ten years to ensure that they have kept up with changes in the marketplace, technology, and business models. Although the Commission's last COPPA Rule review ended in 2013, the Commission is conducting its ten-year review early because of questions that have arisen about the Rule's application to the educational technology sector, to voice-enabled connected devices, and to general audience platforms that host third-party child-directed content. In addition to requesting comment on these issues, the Commission requests comment on the costs and benefits of the Rule, as well as on whether certain sections should be retained, eliminated, or modified. All interested persons are hereby given notice of the opportunity to submit written data, views, and arguments concerning the Rule.

The COPPA Rule, issued pursuant to COPPA, 15 U.S.C. 6501, *et seq.,* became

effective on April 21, 2000, and was revised on January 17, 2013. The Rule imposes certain requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age (collectively, ''operators'').[1] Among other things, the Rule requires that operators provide notice to parents and obtain verifiable parental consent prior to collecting, using, or disclosing personal information from children under 13 years of age. The Rule also requires operators to keep secure the information they collect from children and prohibits them from conditioning children's participation in activities on the collection of more personal information than is reasonably necessary to participate in such activities. Further, the Rule contains a ''safe harbor'' provision enabling industry groups or others to submit to the Commission for approval self-regulatory guidelines that would implement the Rule's protections.

II. Rule Review

COPPA and § 312.11 of the original Rule required the Commission to initiate a review no later than five years after the Rule's effective date to evaluate the Rule's implementation. The Commission commenced this mandatory review on April 21, 2005. After receiving and considering extensive public comment on the Rule, the Commission determined in March 2006 to retain the COPPA Rule without change.[2] In 2010, however, due to changes in the online environment for children, the Commission undertook an extensive Rule review, which culminated in the amendments to the Rule adopted on January 17, 2013.[3] The online environment for children continues to evolve at a rapid pace, including, for example, the significant increase in education technology in the classroom and social media and platforms with third-party content appealing to children. The Commission believes these changes warrant another reexamination of the Rule at this time.

In this document, the Commission poses its standard regulatory review questions to determine whether the Rule should be retained, eliminated, or modified. The Commission also asks whether the 2013 revisions to the Rule have resulted in stronger protections for children and more meaningful parental control over the collection of personal information from children, and whether the revisions have had any negative consequences. It further poses specific questions about the existing sections of the Rule, including:

- Definitions,
- Requirement that operators post notices of their privacy practices,
- Methods of obtaining verifiable parental consent before collecting children's information,
- Security requirements,
- Parental right to review or delete children's information, and
- Safe harbor provisions.

In addition to these questions, the Commission seeks comment on the application of the Rule to the educational technology sector, voice-enabled connected devices, and general audience platforms that host child-directed third-party content. Specifically, the Commission requests comment on whether exceptions to parental consent are warranted for: (1) The use of education technology where the school provides consent for the collection of personal information from the child (*see* Question 23); or (2) the collection of audio files as a replacement for text, where the audio files are promptly deleted (*see* Question 24), in line with the enforcement policy statement issued by the Commission.[4]

Additionally, the Commission seeks comment on whether there are circumstances in which general audience platforms with third-party, child-directed content should be able to rebut the presumption that all users interacting with that content are children (*see* Question 25). If allowed to rebut this presumption, operators of general audience platforms could, in certain circumstances, collect personal information from users on their sites that they determine are age 13 or older.

Finally, the Commission seeks comment on whether the COPPA Rule should be amended to better address websites and online services that may not meet the current definition of ''website or online service directed to children,'' but that have large number of child users (*see* Question 15). For example, should the definition of ''website or online service directed to children'' be amended, consistent with the statute, to cover these types of websites and, if so, what type of changes would be required? Are there other proposed amendments, consistent with the statute, for the Commission to consider to ensure children using these sites and services receive COPPA protections?

III. Questions Regarding the COPPA Rule

The Commission invites members of the public to comment on any issues or concerns they believe are relevant or appropriate to the Commission's review of the COPPA Rule, and to submit written data, views, facts, and arguments addressing the Rule. All comments should be filed as prescribed in the **ADDRESSES** section of this document, and must be received by October 23, 2019. If your comment proposes any modifications to the Rule, please also address whether your proposed modification may conflict with the statutory provisions of COPPA and, if so, whether you propose seeking legislative changes to the Act. The Commission is particularly interested in comments addressing the following questions:

A. General Questions for Comment

1. Is there a continuing need for the Rule as currently promulgated? Why or why not?

a. Since the Rule was issued, have changes in technology, industry, or economic conditions affected the need for or effectiveness of the Rule?

b. What are the aggregate costs and benefits of the Rule?

c. Does the Rule include any provisions not mandated by the Act that are unnecessary or whose costs outweigh their benefits? If so, which ones and why?

2. What effect, if any, has the Rule had on children, parents, or other consumers?

a. Has the Rule benefited children, parents, or other consumers? If so, how?

b. Has the Rule imposed any costs on children, parents, or other consumers? If so, what are these costs?

c. What changes, if any, should be made to the Rule to increase its benefits, consistent with the Act's requirements? What costs would these changes impose?

3. What impact, if any, has the Rule had on operators?

a. Has the Rule provided benefits to operators? If so, what are these benefits?

b. Has the Rule imposed costs on operators, including costs of compliance in time or monetary expenditures? If so, what are these costs?

c. What changes, if any, should be made to the Rule to reduce the costs imposed on operators, consistent with the Act's requirements? How would these changes affect the Rule's benefits?

[1] 16 CFR part 312.

[2] *See* 71 FR 13247 (Mar. 15, 2006).

[3] *See* 78 FR 3972 (Jan. 17, 2013).

[4] *See Enforcement Policy Statement Regarding the Applicability of the COPPA Rule to the Collection and Use of Voice Recordings,* 82 FR 58076 (Dec. 8, 2017).

4. How many small businesses are subject to the Rule? What costs (types and amounts) do small businesses incur in complying with the Rule? How has the Rule otherwise affected operators that are small businesses? Have the costs or benefits of the Rule changed over time with respect to small businesses? What about small businesses that control and process large sets of data? What regulatory alternatives, if any, would decrease the Rule's burden on small businesses, consistent with the Act's requirements?

5. Does the Rule overlap or conflict with any other federal, state, or local government laws or regulations? How should these overlaps or conflicts be resolved, consistent with the Act's requirements?

a. Are there any unnecessary regulatory burdens created by overlapping jurisdiction? If so, what can be done to ease the burdens, consistent with the Act's requirements?

b. Are there any gaps where no federal, state, or local government law or regulation has addressed a problematic practice relating to children's online privacy? Could or should any such gaps be remedied by a modification to the Rule?

6. Has the Rule affected practices relating to the collection and disclosure of information relating to children online? If so, how?

7. Has the Rule affected children's ability to access information of their choice online? If so, how?

8. Has the Rule affected the availability of websites or online services directed to children? If so, how?

a. Has the number or type of websites or online services directed to children changed since the Rule became effective? If so, how? Did the Rule cause these changes?

b. Approximately how many new websites and online services are created each year that are directed to children?

B. Definitions

9. Do the definitions set forth in § 312.2 of the Rule accomplish COPPA's goal of protecting children's online privacy and safety?

10. Are the definitions in § 312.2 clear and appropriate? If not, how can they be improved, consistent with the Act's requirements?

11. The 2013 COPPA Rule amendments made several modifications to the definitions under the Rule, including to the terms ''Collects or collection,'' ''Online contact information,'' ''Operator,'' ''Personal information,'' ''Support for the internal operations of the website or online service,'' and ''website or online service directed to children.'' Have these revised definitions resulted in stronger protections for children's online privacy and safety? Have they had any negative consequences that require revision?

12. The 2013 revised COPPA Rule amended the definition of ''Personal information'' to include, among other items, a ''persistent identifier that can be used to recognize a user over time and across different websites or online services.'' Has this revision resulted in stronger privacy protection for children? Has it had any negative consequences?

13. Should the Commission consider further revision to the definition of ''Personal information''? Are there additional categories of information that should be expressly included in this definition, such as genetic data, fingerprints, retinal patterns, or other biometric data? What about personal information that is inferred about, but not directly collected from, children? What about other data that serve as proxies for personal information covered under this definition? Does this type of information permit the physical or online contacting of a specific individual?

14. Should the definition of ''Support for the internal operations of the website or online service'' be modified? Are there practices in addition to behavioral targeting and profiling that should be expressly excluded from the definition? Should additional activities be expressly permitted under the definition? For example, should the definition expressly include advertising attribution? Advertising attribution is the method used to determine whether a particular advertisement led the user to take a particular step, such as downloading an app.

15. Does § 312.2 correctly articulate the factors to consider in determining whether a website or online service is directed to children? Do any of the current factors need to be clarified? Are there additional factors that should be considered? For example, should the definition be amended, consistent with the statute, to better address websites and online services that do not include traditionally child-oriented activities, but that have large numbers of child users? If so, what types of changes to the definition should be considered? Are there other proposed amendments, consistent with the statute, for the Commission to consider to ensure children using these types of websites and online services receive COPPA protections?

16. Has the 2013 addition, found in part (3) of the definition of ''website or online service directed to children,'' which permits those sites that do not target children as their primary audience to age screen users, resulted in stronger protections for children's privacy? Should the Rule be more specific about the appropriate methods for determining the age of users?

17. What are the implications for COPPA enforcement raised by technologies such as interactive television, interactive gaming, chatbots, or other similar interactive media?

C. Notice

18. Section 312.4 of the Rule sets out the requirements for the content and delivery of operators' notices of their information practices with regard to children.

a. Are the requirements in this Section clear and appropriate? If not, how can they be improved? Should the Rule, for example, more clearly state that an operator's direct notice should include not just the types of personal information collected, but also how the operator intends to use the personal information that is collected? Should the Rule require the notice to include information about the categories of third parties, such as advertisers, that may make use of the information collected? The Rule's direct notice requirement found in § 312.4(c) presupposes that the operator has collected the parent's online contact information. Should the Rule more clearly state the content of direct notices where the operator does not collect a parent's online contact information?

b. Should the notice requirements be clarified or modified in any way to reflect changes in the types or uses of children's information collected by operators or changes in communications options available between operators and parents?

D. Parental Consent

19. Section 312.5 of the Rule requires operators to obtain verifiable parental consent before collecting, using, or disclosing personal information from children, including consent to any material change to practices to which the parent previously consented. This Section further requires operators to make reasonable efforts to obtain this consent, and the efforts must be reasonably calculated to ensure that the person providing consent is the child's parent, taking into consideration available technology.

a. Has the consent requirement been effective in protecting children's online privacy and safety?

b. What data exist on: (1) Operators' use of parental consent mechanisms; (2)

parents' awareness of the Rule's parental consent requirements; or (3) parents' response to operators' parental consent requests?

20. Section 312.5(b)(2) of the Rule provides a non-exhaustive list of approved methods to obtain verifiable parental consent, including: Providing a consent form to be signed by the parent and returned to the operator; requiring a parent to use a credit card, debit card, or other online payment system in connection with a monetary transaction; having a parent call a toll-free number staffed by trained personnel; having a parent connect to trained personnel via video-conference; and verifying a parent's identity by checking a form of government-issued identification against databases of such information. In addition, pursuant to the process set forth in § 312.12(a), the Commission has approved the use of knowledge-based authentication [5] and facial recognition technology.[6] Section 312.5(b)(2) also sets forth a mechanism that operators can use to obtain verifiable parental consent for uses of information other than ''disclosures'' (the ''email plus mechanism''). The email plus mechanism permits the use of an email coupled with additional steps to provide assurances that the person providing consent is the parent, including sending a confirmatory email to the parent following receipt of consent or obtaining a postal address or telephone number from the parent and confirming the parent's consent by letter or telephone call.

a. To what extent are operators using each of the enumerated methods? Please provide as much specific data as possible, including the costs and benefits associated with each method described.

b. Are there additional methods to obtain verifiable parental consent, based on current or emerging technological changes, which should be added to § 312.5 of the Rule? What are the costs and benefits of these additional methods?

c. Should any of the currently enumerated methods to obtain verifiable parental consent be removed from the Rule? If so, please explain which one(s) and why.

d. Should the Commission consider any changes to the Rule to encourage the development of new methods of parental consent?

E. Exceptions to Verifiable Parental Consent

21. COPPA and § 312.5(c) of the Rule set forth eight exceptions to the prior parental consent requirement. Are the exceptions in § 312.5(c) clear and appropriate? If not, how can they be improved, consistent with the Act's requirements?

22. Should the Commission consider additional exceptions to parental consent, consistent with the Act's requirements?

23. In the Statement of Basis and Purpose to the 1999 COPPA Rule, the Commission noted that the Rule ''does not preclude schools from acting as intermediaries between operators and schools in the notice and consent process, or from serving as the parents' agent in the process.'' [7] Since that time, there has been a significant expansion of education technology used in classrooms. Should the Commission consider a specific exception to parental consent for the use of education technology used in the schools? Should this exception have similar requirements to the ''school official exception'' found in the Family Educational Rights and Privacy Act (''FERPA''),[8] and as described in *Protecting Student Privacy While Using Online Educational Services: Requirements and Best Practices*? [9] If the Commission were to amend the COPPA Rule to include such an exception:

a. Should the Rule specify who at the school can provide consent?

b. Should operators be able to use the personal information collected from children to improve the product? Should operators be able to use the personal information collected from children to improve other educational or non-educational products? Should de-identification of the personal information be required for such uses? Is de-identification of such personal information effective at preventing re-identification? What kinds of specific technical, administrative, operational or other procedural safeguards have proved effective at preventing re-identification of de-identified data? Are there instances in which de-identified information has been sold or hacked and then re-identified?

c. Should parents be able to request deletion of personal information collected by operators under such an exception?

d. Should an operator require the school to notify the parent of the operator's information practices and, if so, how should the school provide such notice?

e. Should such an exception result in a preemption of state laws? If so, would that result negatively affect children's privacy?

f. Should the scope of the school's authority to consent be limited to defined educational purposes? Should such purposes be defined, and if so, how? Should operators seeking consent in the school setting be prohibited from using information for particular purposes, such as marketing to students or parents?

24. In 2017, the Commission issued an enforcement policy statement addressing the use of audio files containing a child's voice.[10] The Commission explained that it would not take an enforcement action against an operator for not obtaining parental consent before collecting an audio file with a child's voice when the audio file is collected solely as a replacement for written words, such as to perform a search, so long as the audio file is held for a brief time and used only for that purpose. Should the Commission amend the Rule to specifically include such an exception? If the Commission were to include such an exception, should an operator be able to de-identify these audio files and use them to improve its products? If so, for how long should operators be permitted to retain such de-identified audio files? Is de-identification of audio files effective at preventing re-identification? Are there specific technical, administrative, operational or other procedural safeguards that have proved effective at preventing re-identification of de-identified data? Are there instances in which de-identified information has been sold or hacked and then re-identified?

25. In some circumstances, operators of general audience platforms do not

[5] *See Letter to Imperium, LLC* (Dec. 23, 2013), *https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-grants-approval-new-coppa-verifiable-parental-consent-method/131223imperiumcoppa-app.pdf.*

[6] *See Letter to Jest8 Limited (Trading as Riyo)* (Nov. 18, 2015), *https://www.ftc.gov/system/files/documents/public_statements/881633/151119riyocoppaletter.pdf.*

[7] 65 FR 59888, 59903 (Nov. 3, 1999).

[8] Such requirements would, for example: Prohibit operators from using personal information without the school official's consent; limit operators' use of information to the specified educational purpose and no other commercial purpose; ensure that the school maintains control of the information, including the right to review, correct, and delete the information; and prohibit operators from disclosing the information to third parties.

[9] *See* U.S. Department of Education, Privacy Technical Assistance Center, *Protecting Student Privacy While Using Online Educational Services: Requirements and Best Practices, https://tech.ed.gov/wp-content/uploads/2014/09/Student-Privacy-and-Online-Educational-Services-February-2014.pdf* (2014).

[10] *See Enforcement Policy Statement Regarding the Applicability of the COPPA Rule to the Collection and Use of Voice Recordings,* 82 FR 58076 (Dec. 8, 2017).

have COPPA liability for their collection of personal information from users of child-directed content on their platform uploaded by third parties, absent the platforms' actual knowledge that the content is directed to children. Operators of such platforms therefore may have an incentive to avoid gaining actual knowledge of the presence of child-directed content on their platform. To encourage such platforms to take steps to identify and police child-directed content uploaded by others, should the Commission make modifications to the COPPA Rule? For example, should such platforms that identify and police child-directed content be able to rebut the presumption that all users of the child-directed third-party content are children thereby allowing the platform to treat under and over age 13 users differently? [11] Given that most users of a general audience platform are adults, there may be a greater likelihood that adults are viewing or interacting with child-directed content than on traditional child-directed sites. In considering this issue, the Commission specifically requests comment on the following:

a. Would allowing these types of general audience platforms to treat over and under age 13 users differently encourage them to take affirmative steps to identify child-directed content generated by third parties and treat it in accordance with COPPA?

b. Would allowing such a rebuttal of the presumption that all users are children in this context require a Rule change? If so, would such a Rule change be consistent with the Act?

c. If the Commission were to allow such a rebuttal of the presumption that all users of this content are children, what factors should it consider in determining whether the presumption has been rebutted? What methods could a general audience platform use to effectively rebut the presumption that all users of the third-party child-directed content are children?

d. Could a general audience platform hosting third-party, child-directed content effectively rebut this presumption by doing the following:

i. Taking measures reasonably calculated to identify child-directed content generated by third parties for commercial purposes;

ii. Permitting users that identify themselves through a neutral age gate to create an account on the platform;

iii. Taking measures reasonably calculated, in light of available technology, to ensure that if personal information is to be collected from a user accessing child-directed content, the user is the person who created an account and identified as being 13 or older, and not a child in the household, such as through periodic authentication; and

iv. Providing clear and conspicuous notice at the time the user is interacting with child-directed content of its information collection practices, and separately communicating those information practices through out-of-band notices, such as through online contact information provided as part of the account creation process?

The Commission seeks comment on whether these measures, or any others, could effectively rebut the presumption that all users of this child-directed content are children, and also on the ways in which an operator could implement these measures.

e. What, if any, risk is presented by permitting general audience sites to rebut the presumption that all users of child-directed content are children? Would it prove challenging to reliably distinguish between a parent and a child who accesses content while logged in to a parent's account? In considering whether to permit general audience sites to rebut the presumption, should the Commission consider costs and benefits unrelated to privacy, such as whether children may be exposed to age-inappropriate content if they are treated as an adult?

F. Right of a Parent To Review or Have Personal Information Deleted

26. Section 312.6(a) of the Rule requires operators to give parents, upon their request: (1) A description of the specific types of personal information collected from children; (2) the opportunity to refuse to permit the further use or collection of personal information from the child and to direct the deletion of the information; and (3) a means of reviewing any personal information collected from the child. In the case of a parent who wishes to review the personal information collected from the child, § 312.6(a)(3) of the Rule requires operators to provide a means of review that ensures that the requestor is a parent of that child (taking into account available technology) and is not unduly burdensome to the parent.

a. To what extent are parents exercising their rights under § 312.6(a)(1) to obtain from operators a description of the specific types of personal information collected from children?

b. To what extent are parents exercising their rights under § 312.6(a)(2) to refuse to permit the further use or collection of personal information from the child and to direct the deletion of the information?

c. To what extent are parents exercising their rights under § 312.6(a)(3) to review any personal information collected from the child?

d. Do the costs and burdens to operators or parents differ depending on whether a parent seeks a description of the information collected, access to the child's information, or to have the child's information deleted?

e. Is it difficult for operators to ensure, taking into account available technology, that a requester seeking to review the personal information collected from a child is a parent of that child?

f. Do operators use different processes or procedures to respond to parents who exercise rights under § 312.6(a)? Which processes or procedures are easiest for parents to use? Which are the most difficult? Do any mechanisms exist to facilitate the exercise of these rights with more than one operator at a time?

g. Where operators serve as service providers to schools, should parents be able to request the operators to delete personal information collected by them that are education records, such as grades or test scores?

h. Are the requirements of § 312.6 clear and appropriate? If not, how can they be improved, consistent with the Act's requirements?

G. Prohibition Against Conditioning a Child's Participation on Collection of Personal Information

27. COPPA and § 312.7 of the Rule prohibit operators from conditioning a child's participation in an activity on disclosing more personal information than is reasonably necessary to participate in such activity.

a. Do operators take this requirement into account when shaping their online offerings to children?

b. Has the prohibition been effective in protecting children's online privacy and safety?

c. Is § 312.7 of the Rule clear and appropriate? If not, how could it be improved, consistent with the Act's requirements?

H. Confidentiality, Security, and Integrity of Personal Information

28. Section 312.8 of the Rule requires operators to establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of personal information collected from a child, and to release children's personal

[11] *See* 78 FR 3972, 3984 (Jan. 17, 2013) (''The Commission retains its longstanding position that child-directed sites or services whose primary target audience is children must continue to presume all users are children and to provide COPPA protections accordingly.'').

information only to service providers and third parties who are capable of maintaining the confidentiality, security, and integrity of the personal information, and who provide assurances that they will do so.

a. Have operators implemented sufficient safeguards to protect the confidentiality, security, and integrity of personal information collected from a child?

b. Is § 312.8 of the Rule clear and adequate? If not, how could it be improved, consistent with the Act's requirements? Should the Rule include more specific information security requirements, for example to require encryption of certain personal information?

I. Safe Harbors

29. Section 312.11(g) of the Rule provides that an operator will be deemed in compliance with the Rule's requirements if the operator complies with Commission-approved self-regulatory guidelines (the ''safe harbor'' process).

a. Has the safe harbor process been effective in enhancing compliance with the Rule?

b. Should the criteria for Commission approval of a safe harbor program currently enumerated in § 312.11(b) be modified in any way? To what extent should the Commission consider the financial structure and incentives of organizations operating safe harbors? Is there any evidence that the corporate structure of a safe harbor program impacts its effectiveness? Should the Commission consider applying any restrictions on the types of organizations that may operate safe harbors?

c. Should § 312.11(g) of the Rule, regarding the Commission's discretion to initiate an investigation or bring an enforcement action against an operator participating in a safe harbor program, be clarified or modified in any way?

d. Should any other changes be made to the criteria for approval of self-regulatory guidelines, consistent with the Act's requirements?

e. Should the Commission consider any changes to the safe harbor monitoring process, including any changes to promote greater transparency?

f. Should the Rule include factors for the Commission to consider in revoking approval for a safe harbor program?

IV. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 23, 2019. Write ''COPPA Rule Review, 16 CFR part 312, Project No. P195404,'' 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 *https://www.regulations.gov* website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online. To make sure that the Commission considers your online comment, you must file it at *https://www.regulations.gov* by following the instructions on the web-based form.

If you file your comment on paper, write ''COPPA Rule Review, 16 CFR part 312, Project No. P195404,'' 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. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comments will be placed on the publicly accessible website, *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive personal information, such as your or anyone else's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the Federal Trade Commission Act (''FTC Act''), 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the 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. Once your comment has been posted publicly at *www.regulations.gov*—as legally required by FTC Rule 4.9(c)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants the request.

Visit the FTC website to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 23, 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.

April J. Tabor,

Acting Secretary.

[FR Doc. 2019–15754 Filed 7–24–19; 8:45 am]

BILLING CODE 6750–01–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 23, 43, 45, and 49

RIN 3038–AE32

Certain Swap Data Repository and Data Reporting Requirements; Extension of Comment Period

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On May 13, 2019, the Commodity Futures Trading Commission (Commission) published in the **Federal Register** a notice of proposed rulemaking (NPRM) titled Certain Swap Data Repository and Data Reporting Requirements. The comment period for the NPRM closes on July 29, 2019. The Commission is extending the comment period for this NPRM by an additional 90 days.

DATES: The comment period for the NPRM titled Certain Swap Data Repository and Data Reporting Requirements, published on May 13, 2019 (84 FR 21044), is extended through October 28, 2019.

ADDRESSES: You may submit comments, identified by ''Certain Swap Data Repository and Data Reporting Requirements'' and RIN number 3038–AE32, by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. To avoid possible delays with mail or in-person deliveries, submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *https://comments.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://comments.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT: Benjamin DeMaria, Special Counsel, 202–418–5988, *bdemaria@cftc.gov* or Meghan Tente, Acting Associate Director, 202–418–5785, *mtente@cftc.gov*; Division of Market Oversight, Data and Reporting Branch, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION: On May 13, 2019, the Commission published in the **Federal Register** an NPRM proposing amendments to certain regulations applicable to swap data repositories (SDRs), reporting counterparties, and other market participants.[2] The proposed amendments would, among other things, update requirements for SDRs to verify swap data with reporting counterparties, update requirements to correct swap data errors and omissions, and update and clarify certain SDR operational and governance requirements. The comment period for the NPRM closes on July 29, 2019. As requested by market participants, the Commission is extending the comment period for this NPRM by an additional 90 days.[3] This extension of the comment period will allow interested persons additional time to analyze the proposal and prepare their comments.

Issued in Washington, DC, on July 22, 2019, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Certain Swap Data Repository and Data Reporting Requirements—Commission Voting Summary

On this matter, Chairman Tarbert and Commissioners Quintenz, Behnam, Stump, and Berkovitz voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2019–15810 Filed 7–24–19; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

[2] Certain Swap Data Repository and Data Reporting Requirements, 84 FR 21044 (May 13, 2019).

[3] *See* Letter from International Swaps and Derivatives Association and Securities Industry and Financial Markets Association (June 18, 2019), available at *https://comments.cftc.gov/PublicComments/ViewComment.aspx?id=62139&SearchText=.*

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2019–0629]

Special Local Regulation; Charlevoix Venetian Night Boat Parade; Charlevoix, MI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Charlevoix Venetian Boat Parade on July 27, 2019, to provide for the safety of life on navigable waterways during this event. During the enforcement period, the operator of any vessel in the Round Lake, Charlevoix, MI must comply with directions from the Patrol Commander.

DATES: The regulations will be enforced from 7 a.m. through 11:30 p.m. on July 27, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LT Sean Murphy, Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906–635–3223, email *Sean.V.Murphy@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulation 33 CFR 100.908 for the Charlevoix Venetian Night Boat Parade from 7 a.m. through 11:30 p.m. on July 27, 2019. This action is being taken to provide for the safety of life on navigable waterways during this event. The regulated area for this event is all navigable waters of Round Lake, Charlevoix, MI. During the enforcement period, as reflected in § 100.901(b), the Patrol Commander may direct the anchoring, mooring, or movement of any boat or vessel within the regatta area.

This notice of enforcement is issued under authority of 33 CFR 165.908 and 5 U.S.C. 552(a). In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via marine information broadcasts.

Dated: July 22, 2019.

P.S. Nelson,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2019–15833 Filed 7–24–19; 8:45 am]

BILLING CODE 9110–04–P

Notices

Federal Register
Vol. 84, No. 143
Thursday, July 25, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0037]

Westhoff Vertriebsgesellschaft mbH; Availability of Petition for Determination of Nonregulated Status of Petunias Genetically Engineered for Flower Color

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from Westhoff Vertriebsgesellschaft mbH (Westhoff) seeking a determination of nonregulated status of petunias containing the A1 gene of maize (A1–DFR Petunias), which have been genetically engineered to add a new color (orange) and brilliance. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Westhoff petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before September 23, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0037.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0037, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

The petition and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0037* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

The petition is also available on the APHIS website at: *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS petition 19–099–01p.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3892, email: *cynthia.a.eck@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 19–099–01p) from Westhoff Vertriebsgesellschaft mbH (Westhoff), seeking a determination of nonregulated status of petunias containing the A1 gene of maize (A1–DFR Petunias), which have been genetically engineered to add a new color (orange) and brilliance. The Westhoff petition states that the plant with the new flower color is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, the orange-colored A1–DFR Petunias were initially developed at the Max Plank Institute for Plant Breeding Research and this genetic modification was later unknowingly transferred into other petunia genetic background and released as commercial varieties. Westhoff is seeking a determination of nonregulated status for a few GE varieties of petunias containing DFR gene in the United States.

Data were gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice [1] describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public review and comment, and copies are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above. We are interested in receiving comments regarding potential environmental and interrelated

[1] To view the notice, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129.*

economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. Any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decision-making documents. As part of our decision-making process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation—either an environmental assessment (EA) or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the **Federal Register** announcing the availability of APHIS' EA and plant pest risk assessment.

Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500–1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 19th day of July 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–15837 Filed 7–24–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0040]

Pioneer Hi-Bred International, Inc.; Availability of Petition for Determination of Nonregulated Status for Enhanced Grain Yield Potential and Glufosinate-Ammonium Resistant DP202216 Maize

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from Pioneer Hi-Bred International, Inc. (Pioneer) seeking a determination of nonregulated status of a maize event designated as DP202216, which has been genetically engineered for enhanced grain yield potential and glufosinate-ammonium resistance. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Pioneer petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before September 23, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0040.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0040, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

The petition and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0040* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

The petition is also available on the APHIS website at: *http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml* under APHIS petition 19–101–01p.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Eck, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3892, email: *cynthia.a.eck@usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered ''regulated articles.''

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 19–101–01p) from Pioneer Hi-Bred International, Inc. (Pioneer) seeking a determination of nonregulated status of a maize event designated as DP202216, which has been genetically engineered for enhanced grain yield potential and glufosinate-ammonium resistance. The Pioneer petition states that this maize is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, DP202216 maize was generated using *Agrobacterium*-mediated transformation with plasmid PHP40099 containing the *zmm28* and *mo-pat* gene cassettes. Both the introduced and native *zmm28* genes encode the ZMM28 protein, and the increased and extended expression of the ZMM28 protein results in plants with enhanced grain yield potential. DP202216 maize also contains the phosphinothricin acetyltransferase (PAT) protein, which confers resistance to the herbicidal active ingredient glufosinate-ammonium at current

labeled rates. DP202216 maize has been field tested in the continental United States and Puerto Rico over 9 years in more than 100 separate plantings as authorized under APHIS permits and notifications.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the likelihood of persistence in the environment after completion of the tests. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice [1] describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public review and comment, and copies are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above. We are interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. Any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decisionmaking documents. As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation—either an environmental assessment (EA) or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the **Federal Register** announcing the availability of APHIS' EA and plant pest risk assessment.

Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500–1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 19th day of July 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–15836 Filed 7–24–19; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129.*

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2019–0017]

Notice of Request for a New Information Collection: Permit To Transport Undenatured Inedible Meat Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to create a new information collection for permits to transport domestic undenatured inedible meat products. This is a new information collection with an estimated burden of 87 hours.

DATES: Submit comments on or before September 23, 2019.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2019–0017. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Title: Permit to Transport Undenatured Inedible Meat Products.

OMB Control Number: 0583–XXXX.

Type of Request: Request for a new information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*). This statute mandates that FSIS protect the public by verifying that meat products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS is requesting approval for a new information collection for permits to transport domestic undenatured

inedible meat products. This is a new information collection with an estimated burden of 87 hours.

Under the regulations at 9 CFR 325.11(e), official establishments are to apply in writing to their District Office to obtain a permit for the transport of undenatured inedible meat products in commerce. The application is to indicate the name and address of the applicant, a description of the type of business operations, and the purpose of making such application.

FSIS has made the following estimates based upon an information collection assessment:

Estimate of burden: FSIS estimates that it will take respondents an average of 34.8 minutes per response.

Respondents: Official establishments.

Estimated total number of respondents: 150.

Estimated annual number of responses per respondent: 1.

Estimated Total Annual Burden on Respondents: 87 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email: *Mail:* U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410; *Fax:* (202) 690–7442; *Email: program.intake@usda.gov*.

Persons with disabilities who require alternative means for communication (braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done in Washington, DC.

Carmen M. Rottenberg,

Administrator.

[FR Doc. 2019–15786 Filed 7–24–19; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Saguache-Upper Rio Grande Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Saguache Upper Rio Grande Resource Advisory Committee (RAC) will meet in Del Norte, Colorado. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following website: *https://cloudapps-usda-gov.secure.force.com/FSSRS/RAC_Page?id=001t00000086exUAAQ.*

DATES: The meeting will be held on the following dates:

- Wednesday, August 21, 2019, at 5:00 p.m.,
- Monday, September 16, 2019, at 10:00 a.m., and
- Wednesday, September 18, 2019 at 5:00 p.m.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Rio Grande County Annex, 925 6th Street, Del Norte, Colorado.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Divide Ranger District. Please call ahead at 719–657–3321 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Ariel Chomey, RAC Coordinator, by phone at 719–657–6034 or via email at *ariel.chomey@usda.gov.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339

between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review RAC funding, roles, responsibilities, and operating guidelines,
2. Allow public input on project proposals,
3. Allow time for project proposal presentations,
4. Discuss, recommend, and approve new Title II projects, and
5. Discuss possible future meetings and next steps.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by Friday, August 2, 2019, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Ariel Chomey, RAC Coordinator, 13308 West Highway 160, Del Norte, Colorado 81132; by email to *ariel.chomey@usda.gov,* or via facsimile at 719–657–6035.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: July 3, 2019.

Frank R. Beum,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–15856 Filed 7–24–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[7/9/2019 through 7/18/2019]

Firm name	Firm address	Date accepted for investigation	Product(s)
Rickly Hydrological Company, Inc	1700 Joyce Avenue, Columbus, OH 43219.	7/10/2019	The firm manufactures instruments that measure the flow of liquids.
Yale Sportswear Corporation	1500 Industrial Park Road, Federalsburg, MD 21632.	7/11/2019	The firm manufactures athletic apparel.
Five Clothes, LLC	8251 Melrose Drive, Lenexa, KS 66214	7/11/2019	The firm manufactures women's and girls' swimwear and apparel.
Helmy Associates and Company, Inc	7334 Caribou Street, San Antonio, TX 78238.	7/12/2019	The firm manufactures plastic products.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,

Program Analyst.

[FR Doc. 2019–15768 Filed 7–24–19; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–87–2019]

Approval of Subzone Status; ProAmpac Holdings, Inc.; Neenah and Appleton, Wisconsin

On May 13, 2019, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by Brown County, Wisconsin, grantee of FTZ 167, requesting subzone status subject to the existing activation limit of FTZ 167, on behalf of ProAmpac Holdings, Inc., in Neenah and Appleton, Wisconsin.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (84 FR 22435, May 17, 2019). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 167E was approved on July 22, 2019, subject to the FTZ Act and the Board's regulations, including Section

400.13, and further subject to FTZ 167's 2,000-acre activation limit.

Dated: July 22, 2019.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2019–15825 Filed 7–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–081]

Glycine From the People's Republic of China: Notice of Correction to Final Affirmative Countervailing Duty Determination and Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1121.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2019, the Department of Commerce (Commerce) published the *Final Affirmative Countervailing Duty Determination* on glycine from the People's Republic of China (China).[1] On June 21, 2019, in accordance with section 706(a) of the Tariff Act of 1930, as amended (the Act), Commerce published the *Countervailing Duty Orders* on glycine from China.[2] In both the *Final Affirmative Countervailing Duty Determination* and the *Countervailing Duty Orders,* Commerce made a typographical error with respect to the spelling of the company name of Simagchem Corp., a mandatory respondent subject to the countervailing duty investigation on glycine from China. Specifically, Commerce misspelled the company name as ''Sigmachem Corp'' in the subsidy rate tables of both the *Final Affirmative Countervailing Duty Determination* and the *Countervailing Duty Orders.* The correct spelling of the company name is ''Simagchem Corp.'' As a result, we hereby correct the *Final Affirmative Countervailing Duty Determination* and the *Countervailing Duty Orders.*

Correction

Commerce has corrected the spelling of the company name of Simagchem Corp. in the subsidy rate tables of the *Final Affirmative Countervailing Duty Determination* and the *Countervailing Duty Order.* The estimated subsidy rates remain unchanged. The corrected subsidy rate table is as follows:

Exporter/producer	Subsidy rate (percent)
JC Chemicals Limited	144.01
Simagchem Corp	144.01
All Others	144.01

This correction to the *Final Affirmative Countervailing Duty Determination* and the *Countervailing Duty Orders* is issued and published in accordance with sections 777(i)(1) and 706(a) of the Act.

Dated: July 17, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–15822 Filed 7–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Intent To Develop a Policy for Determining Harmful Algal Bloom (HAB) and Hypoxia Events of National Significance in Marine or Coastal Waters; Opportunity To Provide Information

AGENCY: National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2017 (HABHRCA) provides NOAA with authority to determine that a harmful algal bloom (HAB) or hypoxia event in marine or coastal waters is an event of national significance. NOAA may make this determination on its own initiative or upon the request of the Governor of an affected state. Following an event of national significance determination, NOAA is further authorized to make sums available to the affected state or local government for the purposes of assessing and mitigating the detrimental environmental, economic, subsistence use, and public health effects of the event of national significance. Funds would be subject to the availability of appropriations. The Federal share of the cost of any activity carried out for the purposes described above may not exceed 50 percent of the cost of that activity. NOAA is soliciting comments to inform the development of agency policy for determining HAB and hypoxia events of national significance in marine and coastal waters. NOAA will subsequently issue, in the **Federal Register**, notice of availability of the draft policy and provide an opportunity for formal public comment on the draft policy after it is prepared. Note that HABHRCA provides the United States Environmental Protection Agency (EPA) with comparable authority for determining freshwater hypoxia or HAB events of national significance. The EPA will issue a separate notice to solicit comments on freshwater hypoxia or HAB events.

DATES: Comments must be received on or before Monday, September 9, 2019.

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

- *Electronic Submission:* Public comments can be submitted electronically either through the National Centers for Coastal Ocean Science web page (*https://coastalscience.noaa.gov/*).
- *Email:* You may submit comments via email to *nccos.eventsofsignificance@noaa.gov*. Please indicate ''HAB and hypoxia event of national significance'' in the email subject line.
- *Mail:* Submit all written comments to Caitlin Gould at NOAA, National Centers for Coastal Ocean Science, SSMC–4, Rm. #8237, 1305 East-West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope ''HAB and hypoxia event of national significance.''
- *Instructions:* Comments must be submitted by one of the above methods to ensure that the information is received, documented, and considered by NOAA. Comments sent by any other method, or received after the comment period, may not be considered by NOAA. Do not submit confidential business information or otherwise sensitive or protected information. NOAA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: Maggie Broadwater at (843) 460–9684.

SUPPLEMENTARY INFORMATION: HAB and hypoxic events are some of the most scientifically complex and economically damaging coastal issues challenging our ability to safeguard the health of our

[1] *See Glycine from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 84 FR 18489 (May 1, 2019) (*Final Affirmative Countervailing Duty Determination*).

[2] *See Glycine from India and the People's Republic of China: Countervailing Duty Orders,* 84 FR 29173 (June 21, 2019) (*Countervailing Duty Orders*).

nation's coastal ecosystems. Almost every state now experiences some kind of HAB event, and the number of hypoxic water bodies in the United States has increased over the last century. Recent economic analyses show effects costing hundreds of millions of dollars. Even just one major HAB or hypoxia event can incur tens of millions of dollars to local coastal economies, indicating that the nationwide economic impacts are likely much larger.

In 1998, Congress recognized the severity of these threats and passed the Harmful Algal Bloom and Hypoxia Research and Control Act (HABHRCA 1998; Pub. L. 105–383). The Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2004 (HABHRCA 2004, Pub. L. 108–456) and 2014 (HABHRCA 2014, Pub. L. 113–124) reaffirmed and expanded the mandate for NOAA to advance the scientific understanding and ability to detect, monitor, assess, and predict HAB and hypoxia events. Congress most recently reauthorized and amended HABHRCA through the National Integrated Drought Information System Reauthorization Act of 2018 (Pub. L. 115–423). Section 9 of this Act, cited as the Harmful Algal Bloom and Hypoxia Research and Control Amendments Act of 2017, provides NOAA and the U.S. Environmental Protection Agency with independent authority to make a determination of ''HABs and hypoxia events of national significance.'' Following such a determination, federal officials may ''make sums available to the affected State or local government for the purposes of assessing and mitigating the detrimental environmental, economic, subsistence use, and public health effects of the event of national significance.'' Funds would be subject to the availability of appropriations. This notice focuses only on the authority granted to NOAA and provides interested parties with an opportunity to provide information early in the policy development process for determining HAB and hypoxia events of national significance in marine or coastal waters.

Factors to be considered in making a determination include the toxicity of the HAB, severity of hypoxia, potential for spread, economic impact, relative size in relation to the past five occurrences, and the geographic scope. NOAA is accepting comments to inform the development of guidance for assessing these considerations and whether additional factors should be considered. The determination process optimally will include quantitative and qualitative means of assessment. In particular, NOAA is interested in the following topics:

- The approach that NOAA should use to quantify and qualify the factors identified in the reauthorization of HABHRCA to determine an event of national significance.
  - How NOAA should define and weigh the following statutory parameters:
    - Toxicity of the HAB and severity of hypoxia;
    - Economic impact;
    - Relative size in relation to the past five occurrences of HAB or hypoxia events; that occur on a recurrent or annual basis;
    - Geographic scope, including the potential to spread and affect either a single jurisdiction or multiple municipalities, states, or countries.
  - Based on the statutory parameters above, how should NOAA define significant detrimental environmental, economic, subsistence use, and public health effects and what thresholds should be considered in making a determination.
  - Whether NOAA should consider developing additional criteria, and, if so, how NOAA should quantify or qualify these additional criteria. For example:
    - How NOAA should define an hypoxia event, and whether hypoxia should be defined relative to a set value or specific to an organism, a place, or time;
    - Whether NOAA should consider inclusion of the duration of an event;
    - Whether NOAA should consider the level of public concern and, if so, how to measure that.
- For the parameters described above, the information that a state should provide when requesting a determination and/or funds.
- For the purposes of a determination, and possible assessments and/or mitigation funds, how NOAA should define (A) the start and end of an event; and (B) the geographic extent of the event. Relative to these definitions, whether and how NOAA should establish the point at which states can/may make a funding request for assessment and mitigation assistance.
- For an event that has affected more than one state or shows the potential to do so in the case of an on-going event, whether NOAA should:
  - Make a single determination for an event applicable to all states affected at the time of a determination and any future states affected by the event via geographic expansion, movement, or intensification of the event, or;
  - limit determinations to the area requested by a State based on the then-current location and geographic extent of the event. This alternative could result in multiple state-by-state determinations for a single event.
- How to define subsistence use.
- The definition of the 50% federal/state match, and what contributions may be considered.

To ensure clarity, NOAA requests separate comments for HAB and hypoxia events as it is likely that the factors for each will be considered differently. For more details and background, please refer to this site: *https://coastalscience.noaa.gov/*.

Authority: 33 U.S.C. 4001 *et seq.*

Steven Thur,

Director, National Centers for Coastal Ocean Science, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2019–15820 Filed 7–24–19; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG958

Notice of Availability of the Deepwater Horizon Oil Spill Open Ocean Trustee Implementation Group Draft Restoration Plan 2 and Environmental Assessment: Fish, Sea Turtles, Marine Mammals, and Mesophotic and Deep Benthic Communities; Reopening of Public Comment Period

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

ACTION: Notice of availability; request for comments; reopening of comment period.

SUMMARY: We are reopening the public comment period on our *Deepwater Horizon* Oil Spill Open Ocean Trustee Implementation Group Draft Restoration Plan 2/Environmental Assessment: Fish, Sea Turtles, Marine Mammals, and Mesophotic and Deep Benthic Communities (RP/EA). We opened the original comment period via a May 15, 2019, **Federal Register** notice. That comment period was extended on July 1 and formally closed on July 15, 2019. Due to extenuating weather conditions associated with the recent Hurricane Barry, this notice reopens the comment period through August 2, 2019. Comments submitted previously in response to either of these two **Federal Register** notices, including any comments submitted after July 15, and before the issuance of this notice do not need to be resubmitted.

DATES: Comments must be submitted electronically or postmarked by August 2, 2019.

ADDRESSES:

Obtaining Documents: You may download the Draft RP/EA at: *http://www.gulfspillrestoration.noaa.gov/restoration-areas/open-ocean.* Alternatively, you may request a CD of the Draft RP/EA (see **FOR FURTHER INFORMATION CONTACT** below). Also, you may view the document at any of the public facilities listed in Appendix G.

Submitting Comments: You may submit comments on the Draft RP/EA by one of the following methods:

- *Via the Web: http://www.gulfspillrestoration.noaa.gov/restoration-areas/open-ocean;* or
- *Via U.S. Mail:* U.S. Fish and Wildlife Service, P.O. Box 29649, Atlanta, GA 30345. Please note that mailed comments must be postmarked on or before the comment deadline of August 2, 2019.

FOR FURTHER INFORMATION CONTACT: National Oceanic and Atmospheric Administration—Laurie Rounds, *Laurie.Rounds@noaa.gov,* (850) 934–9284.

SUPPLEMENTARY INFORMATION:

Introduction

In accordance with OPA NRDA regulations in the Code of Federal Regulations (CFR) at 15 CFR part 990, NEPA (42 U.S.C. 4321 *et seq.*), the Consent Decree, and the Final PDARP/PEIS, the Federal and State natural resource trustee agencies (Trustees) have prepared a Draft Restoration Plan 2/Environmental Assessment: Fish, Sea Turtles, Marine Mammals, and Mesophotic and Deep Benthic Communities. The Draft RP/EA analyzes 23 alternatives and proposes 18 preferred alternatives for the following restoration types: Fish and Water Column Invertebrates, Sea Turtles, Marine Mammals, and Mesophotic and Deep Benthic Communities:

Fish and Water Column Invertebrates

- Reduction of Post-Release Mortality from Barotrauma in Gulf of Mexico Reef Fish Recreational Fisheries—Preferred, $30,011,000.
- Better Bycatch Reduction Devices for the Gulf of Mexico Commercial Shrimp Trawl Fishery—Preferred, $17,171,000.
- Communication Networks and Mapping Tools to Reduce Bycatch—Phase 1—Preferred, $4,416,000.
- Restoring for Bluefin Tuna via Fishing Depth Optimization—Preferred, $6,175,000.
- Reduce the Impacts of Ghost Fishing by Removing Derelict Fishing Gear from Marine and Estuarine Habitats—Not Preferred, $6,128,000.

Sea Turtles

- Gulf of Mexico Sea Turtle Atlas—Preferred, $5,700,000.
- Identifying Methods to Reduce Sea Turtle Bycatch in the Reef Fish Bottom Longline Fishery—Preferred, $290,000.
- Developing a Gulf-wide Comprehensive Plan for In-Water Sea Turtle Data Collection—Preferred, $655,000.
- Developing Methods to Observe Sea Turtle Interactions in the Gulf of Mexico Menhaden Purse Seine Fishery—Preferred, $3,000,000.
- Reducing Juvenile Sea Turtle Bycatch Through Development of Reduced Bar Spacing in Turtle Excluder Devices—Preferred, $2,153,000.
- Long-term Nesting Beach Habitat Protection for Sea Turtles—Preferred, $7,000,000.
- Reducing Sea Turtle Entanglement from Recreational Fishing Debris—Not Preferred, $1,113,600.
- Reducing Sea Turtle Bycatch at Recreational Fishing Sites—Not Preferred, $1,329,000.

Marine Mammals

- Reducing Impacts to Cetaceans During Disasters by Improving Response Activities—Preferred, $4,287,000.
- Compilation of Environmental, Threats, and Animal data for Cetacean Population Health Analyses—Preferred, $5,808,500.
- Reduce Impacts of Anthropogenic Noise on Cetaceans—Preferred, $8,992,200.
- Reduce and Mitigate Vessel Strike Mortality of Cetaceans—Preferred, $3,834,000.
- Assessment of Northern Gulf of Mexico Shelf Small Cetacean Health, Habitat. Use, and Movement Patterns—Not Preferred, $4,620,000.

Mesophotic and Deep Benthic Communities

- Mapping, Ground-Truthing, and Predictive Habitat Modeling—Preferred, $35,909,000.
- Habitat Assessment and Evaluation—Preferred, $52,639,000.
- Coral Propagation Technique Development—Preferred, $16,951,000.
- Active Management and Protection—Preferred, $20,689,000.
- Habitat Characterization at Known High Priority Sites—Not Preferred, $21,500,000.

The Open Ocean TIG also analyzes a No Action alternative. One or more alternatives may be selected for implementation by the Open Ocean TIG in the Final RP/EA or in future restoration plans.

Background

For additional background information, see our original **Federal Register** notice, with which we opened the comment period (May 15, 2019; 84 FR 21753). That comment period was extended on July 1 and formally closed on July 15, 2019 (July 1, 2019; 84 FR 31306). Due to extenuating weather conditions associated with the recent Hurricane Barry, this notice reopens that comment period through August 2, 2019.

Invitation to Comment

The Open Ocean TIG seeks public review and comment on the Draft RP/EA (see **ADDRESSES** above). Before including your address, telephone number, email address, or other personal identifying information in your comment, please be aware that your entire comment, including your personal identifying information, will become part of the public record. Comments submitted previously in response to the two **Federal Register** notices, including any comments submitted after July 15, 2019 and before issuance of this notice do not need to be resubmitted.

Authority

The authority of this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*) and its implementing Oil Pollution Act Natural Resource Damage Assessment regulations found at 15 CFR part 990 and the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

Dated: July 19, 2019.

Carrie Selberg,

Deputy Director, Office of Habitat Conservation, National Marine Fisheries Service.

[FR Doc. 2019–15756 Filed 7–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information 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 Telecommunications and Information Administration.

Title: State and Local Implementation Grant Program 2.0 Closeout Documentation.

OMB Control Number: None.

Form Number(s): None.

Type of Request: Regular submission.

Number of Respondents: 46.

Average Hours per Response: 25.

Burden Hours: 1,150.

Needs and Uses: The Middle Class Tax Relief and Job Creation Act of 2012 (Act) (Pub. L. 112–96, H.R. 3630, 126 Stat. 156) was enacted February 22, 2012.[1] The Act meets a long-standing national priority and critical infrastructure need to create a single, interoperable, nationwide public safety broadband network (NPSBN) that allows law enforcement officers, fire fighters, emergency medical service professionals, and other public safety officials to effectively communicate with each other across agencies and jurisdictions. Public safety workers have been hindered in their ability to respond in a crisis due to incompatible communications networks and often outdated communications equipment.

The Act established the First Responder Network Authority (FirstNet) as an independent authority within NTIA and authorizes it to take all actions necessary to ensure the design, construction, and operation of the NPSBN, based on a single, national network architecture.[2]

The Act also charged NTIA with establishing a grant program, the State and Local Implementation Grant Program (SLIGP), to assist State, regional, tribal, and local jurisdictions with identifying, planning, and implementing the most efficient and effective means to use and integrate the infrastructure, equipment, and other architecture associated with the NPSBN to satisfy the wireless broadband and data services needs of their jurisdictions.

In 2013, NTIA originally awarded $116.5 million in grant funds to 54 state and territorial recipients between July 2013 and June 2014. The original grants expired February 28, 2018, and many recipients spent less than expected, leaving leftover funds. NTIA leveraged excess funds of $33.3 million from the original SLIGP grants to make a second round of grant awards, SLIGP 2.0. The SLIGP 2.0 grants provide funding to assist State, regional, tribal, and local jurisdictions to engage effectively with FirstNet and provide it with information needed to continue with planning the NPSBN in an effective and timely manner, as required by the Act. NTIA will use the collection of information to monitor and evaluate how SLIGP 2.0 grant recipients are achieving the core purposes of the program established by the Act. The information collected in the closeout report will ensure that final data effectively assesses the success of SLIGP 2.0 recipients in implementing their project goals.

The publication of this notice allows NTIA to begin the process to request OMB approval to collect information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Affected Public: State, regional, local, and tribal government organizations.

Frequency: Once (at the end of the period of performance).

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.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–15809 Filed 7–24–19; 8:45 am]

BILLING CODE 3510–60–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, July 24, 2019; 9:00 a.m.*

PLACE: CPSC Headquarters, 4330 East-West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting—Closed to the Public.

MATTERS TO BE CONSIDERED: Compliance Matters: Staff will brief the Commission on the status of compliance matters.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504–7479.

* The Commission unanimously determined by recorded vote that Agency business requires calling the meeting without seven calendar days advance public notice.

Dated: July 23, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–15966 Filed 7–23–19; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0087]

Proposed Collection; Comment Request

AGENCY: Office of the DoD Chief Information Officer, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the DoD Chief Information Officer announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 23, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

[1] Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156 (2012) (Act) (codified at 47 U.S.C. 1401 *et seq.*).

[2] 47 U.S.C. 1424, 1426(b)(1).

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DoD's DIB Cybersecurity Activities Office, ATTN: Zachary Gifford, 1550 Crystal Dr., Suite 1000–A, Arlington, VA 22202 or call (703) 604–3167, toll free (855) 363–4227.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Program Point of Contact (POC) Information; OMB Control Number 0704–0490.

Needs and Uses: The information collection requirement is necessary to execute the voluntary Defense Industrial Base (DIB) Cybersecurity (CS) program. DoD will collect business points of contact (POC) information from all DIB CS program participants on a one-time basis, with updates as necessary, to facilitate communications and the sharing of share unclassified and classified cyber threat information.

Affected Public: Business or other for-profit and not-for-profit institutions.

Annual Burden Hours: 312.

Number of Respondents: 935.

Responses per Respondent: 1.

Annual Responses: 935.

Average Burden per Response: 20 minutes.

Frequency: On occasion.

Dated: July 19, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–15769 Filed 7–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0089]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Security Service announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 23, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Security Service, Office of Industrial Policy and Programs, 27130 Telegraph Road, Quantico, VA 22134, ATTN: Laura Aghdam, or call 571–305–6856.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Security Agreement; DD Form 441, DD Form 441–1, OMB Control Number 0704–0194.

Needs and Uses: This information collection requirement is necessary for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to, or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees.

Affected Public: Individuals or households.

Annual Burden Hours: 869.63.

Number of Respondents: 4,021.

Responses per Respondent: 1.

Annual Responses: 4,021.

Average Burden per Response: 24 minutes.

Frequency: On occasion.

Dated: July 19, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–15780 Filed 7–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2019–OS–0088]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant to the Secretary of Defense for Public Affairs, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Assistant to the Secretary of Defense for Public Affairs announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 23, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make

these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to The Office of the Assistant to the Secretary of Defense for Public Affairs, ATTN: CPO (Adrien F. Creecy-Starks), 1400 Defense, The Pentagon, Washington, DC 20301–1400, or call the Directorate for Community and Public Outreach at (703) 695–3845.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Request for Armed Forces Participation in Public Events (Non-Aviation), DD Form 2536 and Request for Military Aerial Support, DD Form 2535; OMB Control Number 0704–0290.

Needs and Uses: This information collection requirement is necessary to evaluate the eligibility of events to receive Armed Forces community relations support and to determine whether requested military assets are available.

Affected Public: State, local, or tribal governments; Federal agencies or employees; for-profit and non-profit institutions; and individuals or households.

Annual Burden Hours: 17,850.

Number of Respondents: 51,000.

Responses per Respondent: 1.

Annual Responses: 51,000 minutes.

Average Burden per Response: 21 minutes.

Frequency: On Occasion.

Dated: July 19, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–15770 Filed 7–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 19–24]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 19–24 with attached Policy Justification and Sensitivity of Technology.

Dated: July 22, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

JUN 2 8 2019

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 19-24 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Germany, through the NATO Support and Procurement Agency (NSPA) acting as its Agent, for defense articles and services estimated to cost $122.86 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Charles W. Hooper
Lieutenant General, USA
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 19–24

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* The Government of Germany through the NATO Support and Procurement Agency (NSPA) acting as its Agent

(ii) *Total Estimated Value:*

Major Defense Equipment *.	$105.23 million
Other	$ 17.63 million
TOTAL	$122.86 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Up to ninety-one (91) AGM–88E Advanced Anti-Radiation Guided Missile (AARGM) Tactical Missiles

Up to eight (8) AGM–88E AARGM Captive Air Training Missiles (CATM)

Non-MDE:

Also included are up to six (6) telemetry/flight termination systems, Flight Data Recorders (FDR), U.S. Government and contractor engineering, technical and logistics support services and miscellaneous

support equipment, and other related elements of logistical and program support.

(iv) *Military Department:* Navy

(v) *Prior Related Cases, if any:* GY–P–GLC, GY–P–GLO, GY–P–GPN, GY–P–ALB

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Annex Attached

(viii) *Date Report Delivered to Congress:* June 28, 2019

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Germany — AGM–88E AARGM Missiles

The Government of Germany has requested to buy, through the NATO Support and Procurement Agency (NSPA) acting as its Agent, up to ninety-one (91) AGM–88E Advanced Anti-Radiation Guided Missile (AARGM) Tactical Missiles, and up to eight (8) AGM–88E AARGM Captive Air Training Missiles (CATM). Also included are up to six (6) telemetry/flight termination systems, Flight Data Recorders (FDR), U.S. Government and contractor engineering, technical and logistics support services and miscellaneous support equipment, and other related elements of logistical and program support. The total estimated cost is $122.86 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a NATO ally, which is an important force for political and economic stability in Europe. It is vital to the U.S. national interests that Germany develops and maintains a strong and ready self-defense capability.

The AGM–88E AARGM is an upgrade to the older generation AGM–88B High-Speed Anti-Radiation Missile (HARM), which Germany first purchased in 1988. The AGM–88E AARGMs in this case will be manufactured using a mixture of new components and older sections from Germany's existing stock of AGM–88Bs provided as Government Furnished Equipment (GFE). Germany will have no difficulty absorbing this equipment and support into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

Germany has requested that the NSPA act as its agent for the FMS procurement and case management to support the AARGM program. The principal U.S. contractor will be NGIS, Ridgecrest, CA. The integration efforts will be via a Direct Commercial Sale (DCS), initiated by the Luftwaffe, between the Tornado Management Agency (NETMA) and the AARGM Original Equipment Manufacturer, Northrop Grumman Innovation Systems, formerly known as Orbital ATK (OA). There are no known offset agreements associated with this potential sale.

Implementation of this proposed sale will require five U.S. government personnel and three contractor representatives to travel to Germany to provide Program Management Reviews. Two visits are planned per year over the next five years.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 19–24

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AGM–88E Advanced Anti-Radiation Guided Missile (AARGM) AGM–88E weapon system is an air-to-ground missile intended to suppress or destroy land or sea-based radar emitters associated with enemy air defenses and provides tactical air forces with a lethal countermeasure to enemy radar directed, surface-to-air missiles, and air defense artillery weapons systems. Destruction or suppression of enemy radars denies the enemy the use of air defense systems, thereby improving the survivability of our tactical aircraft. It uses a multimode seeker that incorporates global positioning system/inertial measurement unit (GPS/IMU) midcourse guidance, a radio frequency (RF) radiation homing receiver, an active millimeter. When assembled, the AGM–88E AARGM is classified SECRET. The AARGM Guidance Section (seeker hardware) and Control Section with the Target Detector is classified CONFIDENTIAL.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the Government of Germany can provide substantially the same degree of protection for the technology being released as the U.S. Government. This sale supports the U.S. foreign policy and national security objectives as outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to Germany.

[FR Doc. 2019–15839 Filed 7–24–19; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9997–05–ORD]

Availability of Synthetic Turf Field Recycled Tire Crumb Rubber Research Under the Federal Research Action Plan Final Report: Part 1—Tire Crumb Rubber Characterization

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of release of action plan part 1 final report.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the release of the *Synthetic Turf Field Recycled Tire Crumb Rubber Research Under the Federal Research Action Plan Final Report: Part 1—Tire Crumb Rubber Characterization*. In February 2016, EPA, Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR), and Consumer Product Safety Commission (CPSC) launched the Federal Research Action Plan (FRAP) on Recycled Tire Crumb Used on Playing Fields and Playgrounds. The goal of this research effort under the FRAP is to characterize potential human exposures to the substances associated with recycled tire crumb rubber used on synthetic turf fields. Playgrounds are addressed separately by CPSC.

Results of the effort are being reported in two parts. Part 1 (this document) communicates the research objectives, methods, results and findings for the tire crumb rubber characterization research (*i.e.,* what is in the material). Part 2, to be released at a later date, will document efforts to characterize potential human exposures to the chemicals found in the tire crumb rubber material while using synthetic turf fields, and will include information from a biomonitoring study initiated by CDC/ATSDR. The timeline and information about the Part 2 report will be posted to the agency's website as it becomes available.

Neither Part 1 nor Part 2 of this study, separately or combined, will constitute an assessment of the risks associated with playing on synthetic turf fields

with recycled tire crumb rubber infill. The results of the research described in both Part 1 and Part 2 of this study should inform future risk assessments.

DATES: This announcement is effective July 25, 2019.

ADDRESSES: The Synthetic Turf Field Recycled Tire Crumb Rubber Research Under the Federal Research Action Plan Final Report: Part 1—Tire Crumb Rubber Characterization, will be available via the internet at *https://www.epa.gov/tirecrumb*.

FOR FURTHER INFORMATION CONTACT: For information on the *Synthetic Turf Field Recycled Tire Crumb Rubber Research Under the Federal Research Action Plan Final Report: Part 1—Tire Crumb Rubber Characterization,* contact Kelly Widener, ORD; telephone: 202–564–6737; or email: *Widener.Kelly@epa.gov*.

SUPPLEMENTARY INFORMATION:

Background Information on the Synthetic Turf Field Recycled Tire Crumb Rubber Research Under the Federal Research Action Plan Final Report: Part 1—Tire Crumb Rubber Characterization

According to the Synthetic Turf Council, there are currently 12,000 to 13,000 synthetic turf fields in the United States, with 1,200 to 1,500 new installations each year. Fields often use recycled tire rubber as infill material, sometimes mixed with sand. Fields are at municipal and county parks; schools, colleges, and universities; professional sports stadiums and practice fields; and military installations. It is estimated that millions of people use or work at these fields each year.

Parents, athletes, schools, and communities have raised concerns about potential health effects. To help address these concerns, the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (CDC/ATSDR) and the U.S. Environmental Protection Agency (EPA), in collaboration with the Consumer Product Safety Commission (CPSC), launched a multi-agency research effort in February 2016.

This multi-agency research effort, known as the Federal Research Action Plan (FRAP) on Recycled Tire Crumb Used on Playing Fields and Playground. The specific FRAP research covered in this report is focused on assessing potential human exposure, which includes conducting research activities to characterize the chemicals associated with recycled tire crumb rubber and to identify the ways in which people may be exposed to those chemicals based on their activities on synthetic turf fields. Also, the research includes characterizing emissions and bioaccessibility to differentiate what is present in the recycled tire crumb rubber from what people may actually be exposed to from recycled tire crumb rubber.

This research was designed to evaluate exposure. Results from this study can be used by others to inform potential risk. Prior to the FRAP being initiated, most studies examining these potential risks have been considered inconclusive or otherwise incomplete. Based upon available literature, this research effort represents the largest tire crumb rubber study conducted in the United States. The information and results from the effort will fill specific data gaps about the potential for human exposure to chemical constituents associated with recycled tire crumb rubber used in synthetic turf fields. The research is not intended to be a risk assessment.

The FRAP includes: (1) A Literature Review/Gap Analysis; (2) Tire Crumb Characterization research; (3) Exposure Characterization research; and (4) A Playground Study. A status report was previously released describing activities of the FRAP as of December 2016 (EPA/600/R–16/364, available at: *https://www.epa.gov/tirecrumb).* The status report included a summary of stakeholder outreach, an overview of the tire crumb rubber manufacturing industry, progress on the research activities, and the final peer-reviewed literature review/gaps analysis (LRGA) white paper.

This *Synthetic Turf Field Tire Crumb Rubber Research Under the Federal Research Action Plan Final Report: Part 1—Tire Crumb Rubber Characterization* summarizes the findings from the Tire Crumb Characterization research effort. While the research under the FRAP is not a risk assessment, the results of the research described in this and future reports will advance the understanding of exposure to inform the risk assessment process. The Part 1 report currently being posted has been through external peer review. A summary of these comments is included in Appendix V. A response-to-peer review comments document will be released along with Part 2.

More information is available at *https://www.epa.gov/tirecrumb* concerning the timeline of the report. Feedback about the study and report can be sent to *recycledtirecrumb@epa.gov.* Information collected as part of the Exposure Characterization research under the FRAP (Part 2) will be released at a later date. Part 2 will include information from a biomonitoring study initiated by CDC/ATSDR to investigate potential exposure to constituents in tire crumb rubber infill. The timeline and information about Part 2 will be posted to the agency's website as it becomes available. CPSC is also conducting the work on playgrounds and results from that effort will be reported separately.

Dated: July 8, 2019.

Timothy Watkins,

Director, National Exposure Research Laboratory.

[FR Doc. 2019–15761 Filed 7–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9997–12–Region 8]

Administrative Settlement Agreement and Order on Consent: Richardson Flat Tailings Site, Park City, Summit County, Utah

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed agreement; request for public comment.

SUMMARY: In accordance with the requirements of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), notice is hereby given of the proposed settlement under CERCLA, between the U.S. Environmental Protection Agency (''EPA''), the U.S. Department of Interior (''DOI''), the State of Utah (''State''), the Florence J. Gillmor Foundation, the Estate of Florence J. Gillmor (collectively, ''Owners''), Summit County, a political subdivision of the State of Utah, and the Snyderville Basin Recreation District, a Special District in the State of Utah (collectively, ''Purchaser'') to settle liabilities at the Richardson Flat Tailings Site in Summit County, Utah.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the agreement. The Agency will consider all comments received and may modify or withdraw its consent to the agreement if comments received disclose facts or considerations that indicate that the agreement is inappropriate, improper, or inadequate.

DATES: Comments must be submitted on or before August 26, 2019.

ADDRESSES: The proposed agreement and additional background information relating to the agreement, as well as the Agency's response to any comments are or will be available for public inspection at the EPA Superfund Record Center, 1595 Wynkoop Street, Denver,

Colorado, by appointment. Comments and requests for a copy of the proposed agreement should be addressed to Matt Hogue, Enforcement Specialist, Superfund and Emergency Management Division, Environmental Protection Agency-Region 8, Mail Code 8SEM–PAC, 1595 Wynkoop Street, Denver, Colorado 80202, (303) 312–6591 and should reference the Richardson Flat Tailings Site.

FOR FURTHER INFORMATION CONTACT: Amelia Piggott, Senior Assistant Regional Counsel, Office of Regional Counsel, Environmental Protection Agency-Region 8, Mail Code 8ORC–LEC, 1595 Wynkoop Street, Denver, Colorado 80202, (303) 312–6410.

SUPPLEMENTARY INFORMATION: The proposed Settlement Agreement allows the Owners to make a cash payment: (1) To EPA and the State to resolve alleged civil CERCLA liability; and (2) to DOI and the State to resolve alleged natural resource damage liability. The proposed Settlement Agreement also facilitates the sale of the Property within the Site to Purchaser as a CERCLA Bona Fide Prospective Purchaser and provides for the performance of Work by Purchaser at the Property and for the payment of certain response costs incurred by the United States at or in connection with the Property. The Owners and Purchaser consent to and will not contest the authority of the United States to enter into the Agreement or to implement or enforce its terms. The Owners and Purchaser recognize that the Agreement has been negotiated in good faith and that the Agreement is entered into without the admission or adjudication of any issue of fact or law.

Dated: July 15, 2019.

Betsy Smidinger,

Division Director, Superfund and Emergency Management Division, U.S. Environmental Protection Agency, Region VIII.

[FR Doc. 2019–15852 Filed 7–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 9, 2019.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Jacquelyn Lee Johnson, as co-trustee of the Zachary M. Johnson, Jr. Irrevocable Trust, Woodbine, Georgia; Ms. Jennifer J. Pope, as co-trustee, Macon, Georgia; Mr. Zachary M. Johnson, III, and Mr. Homer Jackson Johnson, as co-trustees, of the Zachary M. Johnson, Jr. Irrevocable Trust, all of Alma, Georgia;* to retain shares of First Bank Shares of the South East, Inc., and thereby indirectly retain shares of its subsidiary, FNB South (formerly known as First National Bank South), both of Alma, Georgia.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Mark Brase, Windsor, Colorado, individually and as trustee for the William S. Olson Trust, the Beth Brase Appointment Trust, the Christine Vanderliet Appointment Trust, and the Carla Lehman Appointment Trust, all of Windsor, Colorado;* to retain voting shares of O & F Cattle Company, and thereby indirectly retain shares of Nebraska State Bank, both in Oshkosh, Nebraska.

In addition, Christine Vanderliet, Angels Camp, California; Carla Lehman, Denver, Colorado; and Beth Brase, Windsor, Colorado; to join the Olson Family Group and retain voting shares of O & F Cattle Company.

C. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Ted Gerber and Kelly Gerber, both of Grantsburg, Wisconsin;* to retain shares of Cameron Bancorp, Inc., Cameron, Wisconsin, and thereby indirectly retain shares of Community Bank of Cameron, Cameron, Wisconsin.

Additionally, Mary Gerber, Timothy Gerber, Heather Gerber, Caralyn Duerkop, Justin Duerkop, all of Cameron, Wisconsin; Ernest Tyler Gerber, Menasha, Wisconsin; Nancy Gerber, Exeland, Wisconsin; and Mercedes Gerber, Rice Lake, Wisconsin; to retain shares and be approved as members of the Gerber Family group acting in concert, to retain shares of Cameron Bancorp, Inc., Cameron, Wisconsin.

Board of Governors of the Federal Reserve System, July 22, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–15835 Filed 7–24–19; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19BIW; Docket No. CDC–2019–0060]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Evaluation of the DP18–1801 Healthy Schools Program. This evaluation will examine three selected DP18–1801 Healthy Schools Program (DP18–1801) grantees to provide a comprehensive picture of implementation activities, context, successes and challenges, key partnerships, lessons learned, and impact on program outcomes.

DATES: CDC must receive written comments on or before September 23, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0060 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and

Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Evaluation of the DP18–1801 Healthy Schools Program—New—Division of Population Health (DPH) National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention's (CDC) School Health Branch (SHB) requests a three-year OMB approval to conduct a new information collection entitled DP18–1801 Healthy Schools (DP18–1801) Program Evaluation. The DP18–1801 Healthy Schools Program builds upon previous CDC efforts designed to enhance the capacity of state education agencies (SEAs) to adopt and implement evidence-based policies, practices, and programs that support health among the nation's youth. The purpose of the DP18–1801 Healthy Schools Program is to: (1) Increase the number of students who consume nutritious food and beverages (*i.e.,* those aligned with the *Dietary Guidelines for Americans*); (2) increase the number of students who participate in daily physical education and physical activity; and (3) increase the number of students who can effectively manage their chronic health conditions. The evaluation approach is a multisite, embedded case study design, consisting of both process and outcome components, focusing on three 1801 state grantees and a subset of their targeted LEAs and schools. The process component will assess implementation of strategies and activities at the state, local, and school levels and their integration across levels; fidelity of implementation; implementation facilitators and barriers; and contributions of national and state level TA towards program achievements. Three primary data collection methods will be used: (1) Key informant interviews (KII) conducted during in-person site visits or by phone, (2) Web-based surveys, and (3) review of secondary data sources.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
SEA staff	Web-Survey	3	1	75/60	4
	Key-Informant Interview	9	1	75/60	11
LEA staff	Web-Survey	30	1	75/60	38
	Key-Informant Interview	12	1	75/60	15
School staff	Web-Survey	210	1	75/60	263
	Key-Informant Interview	54	1	75/60	68
Total					398

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–15816 Filed 7–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19BJD; Docket No. CDC–2019–0059]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Monitoring and reporting for the Overdose Data to Action Cooperative Agreement.'' This new data collection effort is to collect information from grantees funded under the Overdose Data to Action (CDC–RFA–CE19–1904) funding opportunity. The information collected will be used to monitor the progress on set performance activities, and progress towards stated grant objectives.

DATES: CDC must receive written comments on or before September 23, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2010–0059 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Monitoring and reporting for the Overdose Data to Action Cooperative Agreement—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This new request for a data collection effort is to collect information from grantees funded under the Overdose Data to Action. OMB approval is requested for three years for this new collection. Drug overdose deaths in the United States increased by 18% per year from 2014 to 2016. Opioid overdose deaths have increased fivefold from 1999 to 2016 and in 2017, there were more than 47,000 deaths attributed to opioids. The purpose of the Overdose Data to Action funding opportunity is to support funded grantees in getting high quality, complete, and timely data on opioid prescribing and overdoses, and to use those data to inform prevention and response efforts. There are two required components of this award, a surveillance component, and a prevention component. The intent is to ensure that funded grantees are well equipped to do rigorous work under both components.

The information collected will provide crucial data to CDC for program monitoring and budget tracking, to improve timely CDC-recipient communications, and to inform technical assistance and guidance documents produced by CDC to support program implementation among funded grantees. It will also provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources.

Data collection will include 100% of the funded grantee population, with no sampling. The data will be analyzed using descriptive, summary statistics, and qualitative summary. CDC requests approval for 1,320 annualized burden hours. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Overdose Data to Action funded jurisdictions (State—territories—counties and cities) and their designated delegates.	Evaluation and Performance Measuring Plan Template—Initial Population.	22	1	12	264
	Evaluation and Performance Measuring Plan Template—Annual reporting.	66	1	4	264
	Overdose Prevention Capacity Assessment Tool.	66	1	1	66
	Activity Progress Report and Work Plan Tool—Initial Population.	22	1	20	440
	Activity Progress Report and Work Plan Tool—Annual Reporting.	66	1	4	264
	Surveillance Data Dissemination Plan.	22	1	1	22
Total					1,320

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–15819 Filed 7–24–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–1125]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Ingress/egress and work boot outsole wear investigation at surface mines'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 20, 2019 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Ingress/egress and work boot outsole wear investigation at surface mines—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety & health at work for all people through research and prevention. NIOSH, under Public Law 91–173 as amended by Public Law 95–164 (Federal Mine Safety and Health Act of 1977) has the responsibility to conduct research to improve working conditions and to prevent accidents and occupational diseases in the U.S. mining sector. The goal of the proposed project is to investigate how ingress/egress systems on mobile equipment, and personal protective footwear (boots) used by miners may lead to slips, trips and falls at stone, sand and gravel surface mining facilities. NIOSH is requesting a two-year extension for this data collection.

The project objective will be achieved through two studies. The first study aims to: identify elements of ingress/egress systems on haulage trucks and front end loaders that pose a risk of slips, trips, and falls (STFs) and could lead to STF related injuries; to determine worker behavior associated with STF incidents; and to learn how purchasing/maintenance decisions are made for ingress/egress systems. In the surface mining industry, it is still unclear which component of the ingress/egress system poses the greatest risk for STF. Hence, there is a need to understand where, how, and why STF incidents occur during ingress/egress on mobile equipment.

NIOSH will conduct semi-structured interviews and focus groups with mobile equipment operators, and interviews will be conducted with mine management to explore the issues

identified above. Focus groups will be conducted in a private setting with 4–6 participants using a predefined list of questions to help guide the discussion. Semi-structured interviews will be conducted either in person or over the telephone. Two separate interview guides will be used for mobile equipment operators and mine management to guide the discussion.

For the focus groups and semi-structured interviews, NIOSH will collect basic demographic information including years of mining experience, years of experience with haul trucks/front end loaders, and models of haul trucks/front end loaders operated most often in the past year. The semi-structured interviews and focus groups will be audio recorded for further analysis of the discussion. The semi-structured interviews will last no longer than 60 minutes and the focus groups will last no longer than 90 minutes.

The second study aims to identify changes in tread (wear) on the work boot outsoles and other outsole characteristics of the boot outsole that will be used to develop guidelines for work boot replacement based on measureable features of boot outsoles. This information will also be used in further analysis to determine desirable and undesirable features of work boots based on mine characteristics or job activities. Most mining companies replace footwear at a pre-determined interval or based on appearance and comfort with little knowledge on the actual condition of the boot outsole and its influence on the likelihood of a STF incident. Although there have been attempts to quantify shoe outsole wear in industrial work when the shoe was ready for disposal, there is a lack of knowledge in the mining industry on how quickly the outsoles of work boots wear, what sorts of wear occurs, and how wear patterns influence the likelihood of a STF. This study aims to address this concern through two parts: A longitudinal study of boot outsole wear characteristics and a cross-sectional evaluation of boot outsole characteristics.

For the longitudinal study, NIOSH will provide participants with a pair of new work boots of their choice, in accordance with their respective mine requirements and policies. Afterwards, participants will complete a preliminary survey and provide some basic demographic information, details of their current work boots, and details of STF incidents in the past 3 months. Participants will be requested to wear the supplied boots at work and treat the boots as they would any pair of work boots they would commonly wear at work.

NIOSH researchers will scan the boot outsoles longitudinally, at two to three month intervals for the length of the study. To better understand wear patterns and risks, participants will complete a recurring survey that records hours worked, locations commonly visited, and tasks performed along with details of any near miss or STF events. These self-reports will be collected via survey on a bi-weekly basis. Participants will be offered multiple modalities to respond to the survey (in-person, on paper, over the telephone, via email or using an online survey) to increase response rates. When a participant feels their boots need to be replaced (or when the end of the two-year tracking period has been reached), and at the end of the study, they will complete a final survey assessing why the boots were at the end of their life and will return their boots to NIOSH researchers for further analysis.

For the cross-sectional study, participants' current work boots will be scanned and participants will complete the preliminary survey that includes basic demographic information, details of current work boots, and details of STF events in the past three months.

The results of these research studies will have very different applications, but one goal: Reducing the risks of STF accidents at surface mining facilities. The methods adopted were adequate to address the research questions, and based on a thematic analysis of the data, NIOSH will be able to identify elements of ingress/egress systems on mobile equipment that pose a risk of STFs. The findings of this work were validated against findings from an analysis of MSHA injury data related to front-end loaders (Nasarwanji, Pollard & Porter, 2018). A publication will be drafted based on the results that also includes ways to make mobile equipment.

The extension is requested to help complete data collection for the boot outsole wear study. The results of the boot outsole wear study will be used to inform mine policy and practices by providing miners and mine managers with the knowledge to determine when to replace footwear based on measurable features of the boot outsoles. The total estimated burden hours are 643. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Mobile equipment Operators	Mobile equipment operators focus group guide.	25	1	75/60
Mobile equipment operators	Mobile equipment operator interview guide	10	1	45/60
Mine Management	Mine Management Interview Guide	15	1	45/60
Mine Worker	Screening Questionnaire	50	1	6/60
Mine Worker	Informed consent form(Longitudinal boot outsole study).	50	1	12/60
Mine Worker	Preliminary survey	150	1	15/60
Mine Worker	Recurring survey	50	52	12/60
Mine Worker	Final Survey	50	1	6/60
Mine Worker	Talent and consent waiver	150	1	6/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–15818 Filed 7–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2769]

21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the establishment of a public docket to receive comments from interested parties (including academic institutions, regulated industry, and patient groups) on the Agency's publication of a glossary of terms which is part of the BEST (Biomarkers, EndpointS, and other Tools) Resource Taxonomy. FDA has developed a web page that describes the BEST Resource Taxonomy and links out to the official National Library of Medicine web page for the BEST glossary of terms. Comments on the BEST Resource Taxonomy will help FDA enhance its utility and may assist FDA in developing future versions of this resource and identifying best methods for conveying information about biomarkers, endpoints, and other drug development tools to the general public.

DATES: Submit either electronic or written comments on this notice by September 23, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 23, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–2769 for ''21st Century Cures: Announcing the Establishment of the BEST Resource Taxonomy.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017, *Christopher.Leptak@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3011 of the 21st Century Cures Act (Pub. L. 114–255) added a new section 507 to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357). Section 3011(b)(3)(A) requires FDA to collaborate with biomedical research consortia and other interested parties to ''establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.'' FDA is meeting this legislative requirement through updates to the BEST Resource on the National Library of Medicine website, available at *https://www.ncbi.nlm.nih.gov/books/NBK326791/,* is FDA's response to this

legislative requirement. In Spring 2015, the FDA–NIH (National Institutes of Health) Joint Leadership Council identified the harmonization of terms used in translational science and medical product development as a priority need, with a focus on terms related to study endpoints and biomarkers (see *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm614359.htm*). Working together with the goals of improving communication, aligning expectations, and improving scientific understanding, the two agencies developed the BEST Resource. The current phase of BEST comprises a glossary that clarifies use of important terms in the context of biomarkers and related scientific concepts and describes some of the hierarchical relationships, connections, and dependencies among the terms it contains. For example, the BEST glossary aims to capture distinctions between biomarkers and clinical assessments and to describe their distinct roles in biomedical research, clinical practice, and medical product development. FDA refers the public to the following web page for additional background information as well as a link to the BEST glossary of terms: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm614359.htm.* FDA has previously discussed taxonomy for biomarkers used in drug development at its public meeting on Drug Development Tool Process on December 11, 2018, and invited comment on the BEST taxonomy in guidance published on December 12, 2018, on the evidentiary framework for biomarker qualification.

II. Establishment of a Docket and Issues for Consideration

To help FDA determine the utility of the BEST glossary of terms, develop future iterations, and identify best methods for conveying this information, FDA is soliciting public comments on the BEST glossary that can be found on the following web page: *https://www.ncbi.nlm.nih.gov/books/NBK338448/?report=reader.* The BEST glossary is meant to be a resource that will be periodically updated with additional terms and clarifying information. Specifically, FDA welcomes comments concerning: (1) The utility of the BEST glossary; (2) specific proposed edits, including additions and removal of terms, with a rationale supporting these proposed edits; (3) the best approach for developing future iterations of the glossary; and (4) questions pertaining to the BEST glossary that you would like FDA to address in future communications. As the glossary is refined, the goal is to elaborate on these terms, so they will remain relevant, thus fostering consistent usage. Ultimately, FDA hopes that the BEST glossary will help to accelerate development and refinement of medical products, which will lead to improvements in health outcomes. The Agency will consider comments submitted to the docket as it revises the BEST glossary of terms.

Dated: July 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15827 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0994]

Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group, Inc.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of modified risk tobacco product applications (MRTPAs) for VLN™ King and VLN™ Menthol King, combusted, filtered cigarettes, submitted by 22nd Century Group, Inc.

DATES: Electronic or written comments on the application may be submitted beginning July 25, 2019. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–0994 for ''Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes Submitted by 22nd Century Group Inc.'' 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 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: Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA pursuant to section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in a MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the FD&C Act to make a MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (g)(2). The applicant, 22nd Century Group, Inc., is seeking an order under section 911(g)(2) of the FD&C Act.

FDA may issue an order under section 911(g)(2) of the FD&C Act with respect to a tobacco product that does not satisfy the section 911(g)(1) standard. A person seeking an order under section 911(g)(2) of the FD&C Act must show that:

- Such an order would be appropriate to promote the public health;
- any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for obtaining an order under section 911(g)(1);
- the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;
- the magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;
- testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and
- issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product satisfies the requirements in section 911(g)(2).

FDA is issuing this notice to inform the public that the MRTPAs for the following products submitted by 22nd Century Group, Inc. have been filed and are being made available for public comment:

- MR0000140: VLN™ King
- MR0000141: VLN™ Menthol King

FDA will post the application documents, including any amendments, to its website for the MRTPAs (see section II) for public comment on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents for public comment. FDA intends to establish a closing date for the comment period that is both at least 180 days after the date of this notice and at least 30 days after the final documents from the applications are made available for public comment. FDA will announce the closing date at least 30 days in advance. FDA believes that this comment period is appropriate given the volume and complexity of the applications being posted.

FDA will notify the public about the availability of additional application documents and the comment period closing date via the Agency's web page for the MRTPAs (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. FDA does not intend to issue additional notices in the **Federal Register** regarding the availability of additional application documents, including amendments, or the comment period for these MRTPAs. To receive email alerts, visit FDA's email subscription service management website (*https://updates.fda.gov/subscriptionmanagement*), provide an email address, scroll down to the ''Tobacco'' heading, select ''Modified Risk Tobacco Product Application Update,'' and click ''Submit.'' To encourage public participation

consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

II. Electronic Access

Persons with access to the internet may obtain the documents at *https://www.fda.gov/tobacco-products/advertising-and-promotion/22nd-century-group-inc-modified-risk-tobacco-product-mrtp-applications.*

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15831 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0031]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Clinical Laboratory Improvement Amendments Waiver Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 26, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0598. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Clinical Laboratory Improvement Amendments Waiver Applications

OMB Control Number 0910–0598—Extension

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) (Pub. L. 100–578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary), before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)). Laboratories that perform only tests that are ''simple'' and that have an ''insignificant risk of an erroneous result'' may obtain a certificate of waiver (42 U.S.C. 263a(d)(2)). The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are ''simple'' and have ''an insignificant risk of an erroneous result'' under CLIA (69 FR 22849).

On January 30, 2008, FDA published a guidance document entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and FDA Staff'' (*https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm*). This guidance describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it ''simple''; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

In the **Federal Register** of March 26, 2019 (84 FR 11307), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
CLIA Waiver Application	13	1	13	1,200	15,600	$350,000

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA Waiver Records	13	1	13	2,800	36,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The total number of reporting and recordkeeping hours is 52,000 hours. FDA bases the burden on an Agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 13 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 1,200 hours per waiver application for a total of 15,600 hours for reporting. Based on previous years' experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 36,400 hours.

The total operating and maintenance cost associated with the waiver application is estimated at $350,000. This cost is largely attributed to clinical study costs incurred, which include site selection and qualification, protocol review, and study execution (initiation, monitoring, closeout, and clinical site/subject compensation—including specimen collection for study as well as shipping and supplies).

Our estimated burden for the information collection reflects a decrease of 27 responses and 27 records, and a corresponding overall decrease of 108,000 hours. We attribute this adjustment to a decrease in the average number of submissions we received over the last few years.

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15787 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2775]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2020 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). These fees are effective on October 1, 2019, and will remain in effect through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Tierra Ramsey, Office of Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, email: *oraomdfobudgetformbranch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of FSMA (Pub. L. 111–353) added section 743 to the FD&C Act (21 U.S.C. 379j–31) to provide FDA with the authority to assess and collect fees from, in part: (1) The responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection, to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order, to cover food [1] recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (sections 743(b)(2)(A)(i), (ii), and (iv)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2019, and will remain in effect through September 30, 2020. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's September 2011 ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act,'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-implementation-fee-provisions-section-107-fda-food-safety-modernization-act*), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2020.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2020

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2020. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2020

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2020 cost. The FY 2020 FDA-wide average cost for payroll (salaries and benefits) is $160,885; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $92,828; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,888 per paid staff year, excluding travel costs.

[1] The term ''food'' for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2020 average fully supported cost to $278,602 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2020 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2020 average fully supported cost of $278,602 per FTE by the average number of supported direct FDA work hours in FY 2018—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2018

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	−80
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
26.5 days of general administration	−184
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2020 ($278,602) by the total number of supported direct work hours available for assignment in FY 2018 (1,160) results in an average fully supported cost of $240 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2020.

B. Adjusting FY 2018 Travel Costs for Inflation To Estimate FY 2020 Travel Costs

To adjust the hourly rate for FY 2020, FDA must estimate the cost of inflation in each year for FY 2019 and FY 2020. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2019 inflation rate to be 1.7708 percent; this rate was published in the FY 2019 PDUFA user fee rates notice in the **Federal Register** (August 1, 2018, 83 FR 37504). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.7708 percent for 2019 and 2.3964 percent for 2020 and FDA intends to use these inflation rates to make inflation adjustments for FY 2020 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2020 notice for the PDUFA user fee rates.

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $240 already takes into account inflation as the calculation above is based on FY 2020 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2020 prior to including domestic or foreign travel costs as applicable for the activity. In FY 2018, FDA's Office of Regulatory Affairs (ORA) spent a total of $6,027,291 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 9,976 CFSAN and CVM domestic inspections, which averages a total of $604 per inspection. These inspections average 35.44 hours per inspection. Dividing $604 per inspection by 35.44 hours per inspection results in a total and an additional cost of $17 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2018. To adjust for the $17 per hour additional domestic cost inflation increases for FY 2019 and FY 2020, FDA must multiply the FY 2019 PDUFA inflation rate adjustor (1.017708) times the FY 2020 PDUFA inflation rate adjustor (1.023964) times the $17 additional domestic cost which results in an estimated cost of $18 (rounded to the nearest dollar) per paid hour in addition to $240 for a total of $258 per paid hour ($240 plus $18) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2020 when domestic travel is required.

In FY 2018, ORA spent a total of $3,229,335 on 455 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $7,097 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $7,097 per trip by 120 hours per trip results in a total and an additional cost of $59 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2018. To adjust $59 for inflationary increases in FY 2019 and FY 2020, FDA must multiply it by the same inflation factors mentioned previously in this document (1.017708 and 1.023964), which results in an estimated cost of $61 (rounded to the nearest dollar) per paid hour in addition to $240 for a total of $301 per paid hour ($240 plus $61) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2020 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2020
Hourly rate if domestic travel is required	$258
Hourly rate if foreign travel is required	301

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A)

A. What will cause this fee to be assessed?

The fee will be assessed for a reinspection conducted under section 704 of the FD&C Act (21 U.S.C. 374) to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services' (the Secretary) (and, by delegation, FDA's) satisfaction at a facility that manufactures, processes, packs, or holds food for consumption necessitated as a result of a previous inspection (also conducted under section 704) of this facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the non-compliance was materially related to food safety requirements of the FD&C Act. FDA considers such non-compliance to include non-compliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider non-compliance that is materially related to a food safety requirement to include circumstances where the non-compliance is of a technical nature and not food safety related (*e.g.,* failure to comply with a food standard or incorrect font size on a food label). Determining when non-compliance, other than under sections 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement of the FD&C Act may depend on the facts of a particular situation. FDA intends to issue guidance

to provide additional information about the circumstances under which FDA would consider non-compliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from ''the responsible party for each domestic facility (as defined in section 415(b) (21 U.S.C. 350d(b))) and the United States agent for each foreign facility subject to a reinspection'' to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term ''reinspection'' with respect to domestic facilities as ''1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of th[e] Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.''

The FD&C Act does not contain a definition of ''reinspection'' specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the U.S. agent of a foreign facility subject to a reinspection, the Agency is using the following definition of ''reinspection'' for purposes of assessing and collecting fees under section 743(a)(1)(A), with respect to a foreign facility, ''1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified non-compliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction.''

This definition allows FDA to fulfill the mandate to assess and collect fees from the U.S. agent of a foreign facility in the event that an inspection reveals non-compliance materially related to a food safety requirement of the FD&C Act, causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of non-compliance materially related to a food safety requirement of the FD&C Act. The definition of ''reinspection-related costs'' in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A).

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

V. How Must the Fees Be Paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What Are the Consequences of Not Paying These Fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15817 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0370]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices; Foreign Letters of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 26, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0264. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Export of Medical Devices; Foreign Letters of Approval

OMB Control Number 0910–0264—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or Agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of March 11, 2019 (84 FR 8727), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval—801(e)(2)	33	1	33	3	99	$8,250

[1] There are no capital costs associated with this collection of information.

We have adjusted our burden estimate by decreasing the number of respondents by 5, which has resulted in a corresponding decrease of 15 hours to the currently approved hour burden and $1,250 to the total operating and maintenance costs. This adjustment is based on a decrease in the number of submissions we received over the last few years.

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15790 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0305]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 26, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0768. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0768—Extension

The Tobacco Control Act, enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). Specifically, section 101(b) of the Tobacco Control Act amended the FD&C Act by adding chapter IX (21 U.S.C. 387 through 387u), which provides FDA with tools to regulate tobacco products. Section 901 of the FD&C Act (21 U.S.C. 387a) states that Chapter IX—Tobacco Products applies to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary of Health and Human Services by regulation deems to be subject to this chapter.

The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. On May 10, 2016 (81 FR 28973) FDA issued a final rule to deem products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act. This final rule extended FDA's ''tobacco product'' authorities under Chapter IX to all tobacco products that meet the statutory definition of ''tobacco product'' in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).

Section 910(a)(1) of the FD&C Act (21 U.S.C. 387j(a)(1)) defines a ''new tobacco product'' as a tobacco product that was not commercially marketed in the United States on February 15, 2007, or a modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. An order under section 910(c)(1)(A)(i) of the FD&C Act is required prior to marketing a new tobacco product. This requirement applies unless the product has been shown to be substantially equivalent to a valid predicate product or is exempt from substantial equivalence.

Section 910(b) of the FD&C Act states that a premarket tobacco application (PMTA) shall contain full reports of all investigations of health risks; a full statement of all components, ingredients, additives, and properties, and of the principle or principles of operation of such tobacco product; a full description of methods of manufacturing and processing (which includes a listing of all manufacturing, packaging, and control sites for the product); an explanation of how the product complies with applicable tobacco product standards; samples of the product and its components; and labeling.

FDA also encourages persons who would like to study their new tobacco product to meet with the Office of Science in the Center for Tobacco Products (CTP) to discuss their investigational plan. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss agenda items.

When the deeming final rule published, FDA revised the following information collections that added deemed products to these collections: Tobacco Product Establishment Registration and Submission of Certain Health Information (OMB control number 0910–0650); Tobacco Health Document Submission (OMB control number 0910–0654); Exemptions from Substantial Equivalence Requirements (OMB control number 0910–0684); Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product (OMB control number 0910–0673); Electronic Importer's Entry Notice (OMB control number 0910–0046); Exports: Notification and Recordkeeping Requirements (OMB control number 0910–0482); and Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (OMB control number 0910–0775).

In the **Federal Register** of April 22, 2019 (84 FR 16673), FDA published a 60-day notice requesting public comment on the extension of collection of information ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act.'' FDA received one comment that was Paperwork Reduction Act (PRA) related.

The commenter noted that they would like to see the associated collections that the deeming rule revised. FDA appreciates the comment addressing the associated deemed product information collections. FDA notes that in the PRA section of the deeming final rule (81 FR 28973 at 29076) all the revised OMB information collection control numbers and their revised burdens were all listed. Per the comment, we have added a listing of all the collections the final rule revised.

The commenter also notes that the burdens associated with deemed products are not all included in this notice even though the notice ''appears intended to present a comprehensive set of burden estimates and analyses for information collection activities associated with . . . the Deeming Rule.'' FDA notes that this notice is not intended to cover all information collection reviews associated with the deeming rule. Instead, this notice only covers the information collections that did not already have an approved collection prior to the deeming final rule. For the collections that existed prior to the deeming final rule, FDA added the new associated deeming-related burdens to these previously approved OMB control numbers. We also note that some of the estimates from the PRA section of the deeming rule may have changed since the final rule published. If any estimates have changed, these changes have been published in the **Federal Register** through the process associated with renewing PRA collections.

The comment also mentions the omission of the burden associated with the submission of harmful and potentially harmful constituents (HPHC) listings. FDA notes that we have not yet sought OMB approval of the burden associated with listing and reporting HPHCs for deemed products. On March 8, 2019, FDA revised the ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule'' guidance (*https://www.fda.gov/media/105346/download*) and the related Small Entity Compliance Guide entitled ''FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-deems-certain-tobacco-products-subject-fda-authority-sales-and-distribution-restrictions-and*). This revision extends the HPHCs reporting compliance date to a date that is 6 months after the publication date of a final guidance regarding HPHC reporting under section 904(a)(3) of the FD&C Act (21 U.S.C. 287d(a)(3)) and 9 months after that publication date for small tobacco product manufacturers. For products entering the market after the publication date of the final guidance, manufacturers must submit their HPHC report 90 days prior to marketing the products under section 904(a)(3).

In the preamble to the final deeming rule, FDA indicated that it intends to

issue guidance regarding HPHC reporting (and later a testing and reporting regulation under section 915 of the FD&C Act (21 U.S.C. 387o)) with enough time for manufacturers to report, given the original 3-year compliance period. At this time, FDA has not published a final HPHC reporting guidance and as a result, we are providing a revised compliance date based on when a final HPHC reporting guidance is issued.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application) and 21 CFR 25.40 Environmental Assessments:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Electronic Nicotine Delivery Systems (ENDS) Liquids and Delivery Systems (Including Importers))	200	3.75	750	1,713	1,284,750
Total Hours Obtaining an FDA Order Authorizing Marketing of Tobacco Product (the application)	.....	.....	.....	.....	1,284,750
Request for Meeting with CTP's Office of Science to Discuss Investigational Plan:					
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (Electronic Nicotine Delivery Systems (ENDS) Liquids and Delivery Systems (Including Importers))	200	1	200	4	800
Total Hours Request for Meeting with CTP's Office of Science to Discuss Investigational Plan	.....	.....	.....	.....	800
Total Hours ''Applications for Premarket Review of New Tobacco Products''	.....	.....	.....	.....	1,285,550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment in accordance with the requirements of 21 CFR 25.40, for a total of 1,713 hours per PMTA application. This average represents a wide range of hours that will be required for these applications under different circumstances, with a small number requiring more hours (*e.g.,* as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (*e.g.,* as few as 50 hours for applications for products that are very similar to other new products). A PMTA may require one or more types of studies including chemical analysis, nonclinical studies, and clinical studies. FDA also estimates the number of PMTAs that FDA expects to receive annually will be 750 (642 ENDS Liquids and 108 ENDS Delivery Systems).

For tobacco products already on the market at the time of the final rule, much of the information required to support a PMTA may be obtained from previously published research on similar products. Therefore, FDA expects that a large portion of applications may be reviewed with no or minimal new nonclinical or clinical studies being conducted to support an application. In contrast, nonclinical and clinical studies may be required for market authorization of a new product for which there is limited understanding of its potential impact on the public health. The range of hours involved to compile these two types of applications would be quite variable.

FDA anticipates that the 200 potential respondents to this collection may need to meet with CTP's Office of Science to discuss their investigational plans. To request this meeting, applicants should compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 4 hours to compile this information, for a total of 800 hours additional burden.

Therefore, the total annual burden for submitting PMTA applications is estimated to be 1,285,550 hours. FDA's estimates are based on the corresponding information collection estimates and an assumption that manufacturers would submit applications for the premarket review of tobacco products.

In § 1143.3(c) (21 CFR 1143.3(c)) an exemption is provided to the manufacturer of a product that otherwise would be required to include the warning statement in § 1143.3(a)(1) on its packages and in its advertisements, *i.e.,* ''WARNING: This product contains nicotine. Nicotine is an addictive chemical.'' This warning is required to appear on at least 30 percent of the two principal display panels of the package and on at least 20 percent of the area of the advertisement.

To obtain an exemption from this requirement, a manufacturer is required to certify to FDA that its product does not contain nicotine and that the manufacturer has data to support that assertion. For any product that obtains this exemption, § 1143.3(c) requires that the product bear the statement: ''This product is made from tobacco.'' The parties that package and label such products will share responsibility for ensuring that this alternative statement is included on product packages and in advertisements.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Certification Statement	5	1	5	20	100
Total Exemptions From the Required Warning Statement Requirement					100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated average burden per response is based on currently approved information collection estimates. The estimated hours listed in the burden table for certification submissions reflect the time needed to test the product for nicotine and to prepare and submit the self-certification request. FDA expects that these types of certifications will be rare and estimates that the Agency will receive on average five submissions per year.

FDA concludes that the labeling statements in §§ 1143.3(a)(1) and 1143.5(a)(1) and the alternative statement in § 1143.3(c) (*i.e.,* ''This product is made from tobacco'') are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501–3520). Rather, these labeling statements are a ''public disclosure'' of information originally supplied by the Federal government to the recipient for the purpose of ''disclosure to the public'' (5 CFR 1320.3(c)(2)).

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Cigar warning plan	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Manufacturers, Importers, and Retailers	10	1	10	120	1,200
Total Cigar Warning Plan					1,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The requirement for submission of warning plans for cigar products, and the specific requirements relating to the random display and distribution of required warning statements on cigar packaging and quarterly rotation of required warning statements in alternating sequence on cigar product advertising, appear in § 1143.5(c).

The six warnings for cigars (five specifically for cigars and the one addictiveness warning) are required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a warning plan submitted to and approved by FDA. For advertisements, the warning statements must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to and approved by FDA.

FDA published a final guidance in August 2018 (*https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM534739.pdf*) to assist manufacturers, importers, distributors, and retailers of cigars with the submission of warning plans. FDA will work with the submitters to ensure that the plans submitted meet the established criteria for approval under 21 CFR part 1143.

The warning statements on cigar packaging must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold and are required to be randomly distributed in all areas of the United States in which the product is marketed in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

FDA also requires that the required warning statements be rotated quarterly in alternating sequence in each advertisement for each brand of cigar, regardless of whether the cigar is sold in product packaging. This rotation of warning statements in cigar advertisements also must be done in accordance with a warning plan submitted by the responsible cigar manufacturer, importer, distributor, or retailer to and approved by FDA.

The burden estimates are based on FDA's experience with cigar warning plans, smokeless warning plans associated information collection (OMB control number 0910–0671), as well as warning plans for cigarettes submitted to the Federal Trade Commission prior to the implementation of the Tobacco Control Act on June 22, 2009.

We estimate 10 entities will submit warning plans, and it will take an average of 120 hours per respondent to prepare and submit a warning plan for packaging and advertising for a total of 1,200 hours.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Small-Scale Manufacturer Reporting	75	1	75	2	150
Total Small-Scale Manufacturer Report					150

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Generally, FDA considers a ''small-scale tobacco product manufacturer'' to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with such manufacturer. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues. FDA does not believe many manufacturers who fit the criteria of a small-scale tobacco product manufacturer would submit the voluntary information.

FDA estimates that there are approximately 75 small-scale manufacturers who will voluntarily submit information. FDA believes it will take respondents 2 hours to voluntarily submit information regarding employment and revenues for a total of 150 hours.

The total estimated burden for this information collection is 1,286,950 reporting hours, and 1,040 annual responses. Our estimated burden for the information collection reflects an overall decrease of 39,050 hours and a corresponding decrease of 315 responses. We attribute this adjustment to updated information in the number of submissions we received over the last few years.

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15791 Filed 7–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0349]

National Offshore Safety Advisory Committee

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The National Offshore Safety Advisory Committee and its Subcommittee will meet in Katy, Texas to discuss Committee matters relating to the safety of operations and other matters affecting the offshore oil and gas industry. All meetings will be open to the public.

DATES:

Meetings: The National Offshore Safety Advisory Committee and its Subcommittee will meet on Tuesday, September 10, 2019 and on Wednesday, September 11, 2019. The Use of Offshore Supply Vessels and Other Non-Purpose Built Vessels for Restoration/Recovery Activities Subcommittee will meet on Tuesday, September 10, 2019 from 1 p.m. to 4 p.m. The full Committee will meet on Wednesday, September 11, 2019, from 8 a.m. to 6 p.m. (All times are Central Time). Please note that these meetings may close early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received by Committee members before the meetings, submit your written comments no later than August 27, 2019.

ADDRESSES: All meetings will be held at DNV GL USA Facility, 1400 Ravello Drive, Katy, Texas 77449.

For information on facilities or services for individuals with disabilities or to request special assistance at the meetings, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meetings, but if you want Committee members to review your comment before the meetings, please submit your comments no later than August 27, 2019. We are particularly interested in the comments in the ''Agenda'' section below. You must include ''Department of Homeland Security'' and docket number USCG–2019–0349. Written comments may also be submitted using the Federal eRulemaking Portal at *http://www.regulations.gov.* If you encounter technical difficulties with comments submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. For more information about the privacy and docket, review the Privacy and Security Notice for the Federal Docket Management System at *https://www.regulations.gov/privacyNotice.*

Docket Search: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* and insert ''USCG–2019–0349)'' in the ''Search'' box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Commander Myles Greenway, Designated Federal Officer of the National Offshore Safety Advisory Committee, Commandant (CG–OES–2), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE, Stop 7509, Washington, DC 20593–7509; telephone (202) 372–1410, fax (202) 372–8382 or email: *myles.j.greenway@uscg.mil,* or Mr. Patrick Clark, telephone (202) 372–1358, fax (202) 372–8382 or email *patrick.w.clark@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is in compliance with the *Federal Advisory Committee Act,* (Title 5 U.S.C. Appendix). The National Offshore Safety Advisory Committee provides advice and recommendations to the Department of Homeland Security on matters relating to activities directly involved with or in support of the exploration of offshore mineral and

energy resources insofar as they relate to matters within Coast Guard jurisdiction.

Agenda

Day 1

The National Offshore Safety Advisory Committee's Use of Offshore Supply Vessels and Other Non-Purpose Built Vessels for Restoration/Recovery Activities Subcommittee will meet on September 10, 2019 from 1:00 p.m. to 4:00 p.m. (Central Time) to review, discuss and formulate recommendations to be presented to the full Committee during the September 11, 2019 public meeting.

Day 2

The National Offshore Safety Advisory Committee will hold a public meeting on September 11, 2019 from 8 a.m. to 6 p.m. (Central Time) to review and discuss the progress of, and any reports and recommendations received from the above listed subcommittee from their deliberations. The Committee will then use this information and consider public comments in discussing and formulating recommendations to the United States Coast Guard. Public comments or questions will be taken at the discretion of the Designated Federal Officer during the discussion and recommendation portions of the meeting and during the public comment period, see Agenda item (5). A complete agenda for the September 11, 2019 full Committee meeting is as follows:

(1) Welcoming remarks.

(2) General administration and acceptance of minutes from the March 20, 2019 National Offshore Safety Advisory Committee public meeting.

(3) Current business—Presentation and discussion of progress from the Use of Offshore Supply Vessels and Other Non-Purpose Built Vessels for Restoration/Recovery Activities Subcommittee.

(4) New Business—

(a) Status of National Offshore Safety Advisory Committee Recommendations to the U.S. Coast Guard.

(b) Presentation and discussion on future trends anticipated by classification societies.

(c) Presentation on Industry views of the new Well Control Rule.

(d) International Association of Drilling Contractors Presentation on trade association views of the new Well Control Rule.

(e) Bureau of Safety and Environmental Enforcement—Regulator view of the new Well Control Rule.

(f) Maritime Administration Update.

(5) Public comment period.

A copy of all meeting documentation will be available at *https://homeport.uscg.mil/missions/ports-and-waterways/safety-advisory-committees/nosac/meetings* no later than August 27, 2019. Alternatively, you may contact Commander Myles Greenway or Mr. Patrick Clark as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments or questions will be taken throughout the meeting as the Committee discusses the issues and prior to deliberations and voting. There will also be a public comment period at the end of the meeting. Speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the period allotted, following the last call for comments. Contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section above to register as a speaker.

Dated: July 28, 2019.

Jeffery G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2019–15788 Filed 7–24–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORB00000.L10200000. BS0000.LXSSH1060000. 19X.HAG 19–0089]

Notice of Public Meeting for the Southeast Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Southeast Oregon Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Southeast Oregon RAC will meet via teleconference on Wednesday, August 21, 2019, from 9:00 a.m. to noon Mountain Time.

ADDRESSES: The telephone conference line number for the meeting is 1–877–922–8971, Participant Code: 5867492.

FOR FURTHER INFORMATION CONTACT: Larisa Bogardus; Public Affairs Officer; 3100 H Street, Baker City, Oregon 97814; telephone: 541–523–1407; email: *lbogardus@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Ms. Bogardus during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Southeast Oregon. The members provide diverse perspectives in commodity, conservation, and general interests.

The meeting will include review and discussion of potential formal comments regarding the Southeastern Oregon Resource Management Plan Amendment Draft Environmental Impact Statement as part of the public participation process.

A final agenda will be posted online at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/southeast-oregon-rac* at least 1 week prior to the teleconference.

All meetings are open to the public in their entirety and a public comment period is scheduled for 10:15 a.m. to 10:45 a.m. The public may address the RAC during the public comment period or submit a written statement no later than August 16, 2019. Written comments should be sent to the BLM Public Affairs Officer at the address listed in the **FOR FURTHER INFORMATION CONTACT** section of this Notice. All comments received will be provided to the Southeast Oregon RAC prior to the meeting. 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

Jeffrey Rose,

Burns District Manager.

[FR Doc. 2019–15841 Filed 7–24–19; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–D–COS–POL–28210; PPWODIREP0; PPMPSAS1Y.YP0000]

Notice of the August 27, 2019, Meeting of the National Park System Advisory Board

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the National Park System Advisory Board (Board) will meet as noted below.

DATES: The meeting will be held on Tuesday, August 27, 2019, from 9:30 a.m. to 5:15 p.m. (Eastern).

ADDRESSES: The meeting will be conducted in the South Penthouse of the Stewart Lee Udall Department of the Interior Building, 1849 C Street NW, Washington, DC 20240, telephone 202–354–3950.

FOR FURTHER INFORMATION CONTACT: Joshua Winchell, Staff Director, National Park System Advisory Board, Office of Policy, National Park Service, 1849 C Street NW, Mail Stop 2659, Washington, DC 20240, telephone (202) 513–7053, or email *itmd_joshuawinchell@nps.gov.*

SUPPLEMENTARY INFORMATION: The Board has been established by authority of the Secretary of the Interior (Secretary) under 54 U.S.C. 100906, and is regulated by the Federal Advisory Committee Act.

The Board will convene its business meeting at 9:30 a.m. and adjourn at 5:15 p.m. During the morning session, the Board will be addressed by Secretary of the Interior David Bernhardt, and other senior Department of the Interior and National Park Service leaders. During the afternoon session, the Board will be briefed by National Park Service officials on the organization, programs, and priorities of the National Park Service; and the Board will attend to housekeeping matters, including the election of the chair and vice chair, and establishment of committees under the Board. There will also be a public comment period. The final agenda will be posted to the Board's website prior to the meeting at *https://www.nps.gov/advisoryboard.htm.*

The meeting is open to the public, but preregistration is required due to security requirements in the building and limited seating. Any individual who wishes to attend the meeting should register via email at Joshua Winchell *itmd_joshuawinchell@nps.gov,* or telephone (202) 513–7053. Interested persons may choose to make a public comment at the meeting during the designated time for this purpose. Members of the public may also choose to submit written comments by mailing them to Joshua Winchell, Staff Director, National Park System Advisory Board, Office of Policy, National Park Service, 1849 C Street NW, MS 2659, Washington, DC 20240, or via email at *itmd_joshuawinchell@nps.gov.* Individuals who plan to attend and need special assistance, such as sign language interpretation, should contact the NPS as provided above.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2019–15815 Filed 7–24–19; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1073]

Certain Thermoplastic Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing Same II; Termination of Investigation With a Finding of No Violation of Section 337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to terminate the above-captioned investigation with a finding of no violation of section 337 of the Tariff Act of 1930.

FOR FURTHER INFORMATION CONTACT: Sidney A. Rosenzweig, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–708–2532. 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 (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on October 11, 2017, based on a complaint filed on September 5, 2017, by Intellectual Ventures II LLC of Bellevue, Washington (''IV''). 82 FR 47250 (Oct. 11, 2017). The complaint alleges a violation of section 337 by reason of infringement of certain claims of U.S. Patent Nos. 7,683,509 (''the '509 patent''); 7,928,348 (''the '348 patent''); 7,154,200 (''the '200 patent''); 7,067,944 (''the '944 patent''); and 7,067,952 (''the '952 patent''). The notice of investigation names as respondents Aisin Seiki Co., Ltd. of Aichi, Japan; Aisin Holdings of America, Inc. of Seymour, Indiana; Aisin Technical Center of America, Inc. of Northville, Michigan; and Aisin World Corporation of America of Northville, Michigan (collectively, ''Aisin'' or ''Aisin Seiki''); Bayerische Motoren Werke AG of Munich, Germany, BMW of North America, LLC of Woodcliff Lake, New Jersey and BMW Manufacturing Co., LLC of Greer, South Carolina (collectively, ''BMW''); Denso Corporation of Aichi, Japan and Denso International America, Inc. of Southfield, Michigan (''collectively, DENSO''); Honda Motor Co., Ltd. of Tokyo, Japan; Honda North America, Inc., of Torrance, California; American Honda Motor Co., Inc. of Torrance, California; Honda of America Mfg., Inc. of Marysville, Ohio; Honda Manufacturing of Alabama, LLC of Lincoln, Alabama; and Honda R&D Americas, Inc. of Torrance, California (collectively, ''Honda''); Mitsuba Corporation of Gunma, Japan and American Mitsuba Corporation of Mount Pleasant, Michigan (collectively, ''Mitsuba''); Nidec Corporation of Kyoto, Japan and Nidec Automotive Motor Americas, LLC of Auburn Hills, Michigan (collectively, ''Nidec''); and Toyota Motor Corporation of Aichi

Prefecture, Japan; Toyota Motor North America, Inc. of New York, New York; Toyota Motor Sales, U.S.A., Inc. of Torrance, California; Toyota Motor Engineering & Manufacturing North America, Inc. of Erlanger, Kentucky; Toyota Motor Manufacturing, Indiana, Inc. of Princeton, Indiana; and Toyota Motor Manufacturing, Kentucky, Inc. of Georgetown, Kentucky (collectively, ''Toyota''). The Office of Unfair Import Investigations (''OUII'') was also named a party in this investigation.

The Commission previously terminated the investigation in part with respect to respondents BMW, DENSO, Mitsuba, and Nidec, as well as the '200, '944, and '952 patents. Notice (Apr. 18, 2018) (determining not to review Order No. 22 (Mar. 16, 2018)); Notice (May 4, 2018) (determining not to review Order No. 29 (Apr. 10, 2018)); Notice (May 4, 2018) (determining not to review Order No. 31 (Apr. 16, 2018)); Notice (May 11, 2018) (determining not to review Order No. 33 (Apr. 23, 2018)); Notice (June 19, 2018) (determining not to review Order No. 39 (May 21, 2018)); Notice (Aug. 15, 2018) (determining not to review Order No. 46 (July 19, 2018)); Notice (Aug. 15, 2018) (determining not to review Order No. 47 (July 24, 2018)); Notice (Aug. 27, 2018) (determining not to review Order No. 48 (Aug. 13, 2018)). Thus, the remaining respondents in this investigation are Aisin, Honda, and Toyota (collectively, ''Respondents''), and the remaining asserted patents are the '509 and '348 patents (collectively, the ''asserted patents'').

On November 13, 2018, the presiding administrative law judge (''ALJ'') issued a final initial determination (''ID''), finding no violation of section 337 with respect to the '509 and '348 patents. Specifically, the ID finds that the accused products infringe claims 14 and 15 of the '509 patent, but do not infringe claims 24–27 of the '348 patent. With respect to both patents, the ID finds that IV has not satisfied the domestic industry requirement of section 337(a)(2) & (a)(3), nor have Respondents established that any asserted claim is invalid for obviousness.

On November 27, 2018, the ALJ issued a Recommended Determination (''RD'') on remedy, the public interest, and bonding, recommending, should the Commission find a violation: (1) The issuance of a limited exclusion order directed to certain infringing thermoplastic-encapsulated electric motors, components thereof, and products and vehicles containing same; (2) the issuance of cease and desist orders against Aisin and Toyota; and (3) imposition of a bond of zero percent for infringing products that are imported during the period of Presidential review.

Also, on November 27, 2018, IV filed a petition for review, and Respondents filed a contingent petition for review, each challenging various findings in the final ID. On December 6, 2018, IV, Respondents, and OUII filed responses to the petitions for review.

On December 14, 2018, Respondents filed a notice that, on December 12, 2018, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office issued four final written decisions finding that every claim asserted against Respondents in this investigation is unpatentable on invalidity grounds.

On January 7, 2019, the Alliance of Automobile Manufacturers and the Association of Global Automakers filed a joint public-interest submission.

On February 19, 2019, the Commission determined to review the ID in its entirety, and solicited further briefing from the parties on certain issues, and briefing from the parties and the public on remedy, the public interest and bonding. On March 1, 2019, the parties filed opening briefs, and on March 8, 2019, the parties filed reply briefs.

Having examined the record of this investigation, including the final ID and the parties' submissions, the Commission has determined that IV has failed to satisfy the domestic industry requirement of section 337(a)(2) & (a)(3), 19 U.S.C. 1337(a)(2) & (a)(3). Accordingly, the Commission has determined to terminate the investigation with a finding of no violation of section 337. The Commission, therefore, does not reach and takes no position on the other issues raised in the parties' petitions for Commission review.

The reasons for the Commission's determination are set forth more fully in the Commission's opinion.

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: July 19, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–15784 Filed 7–24–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–029]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: August 2, 2019 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–609 and 731–TA–1421 (Final) (Steel Trailer Wheels from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by August 22, 2019.

5. Vote on Inv. Nos. 701–TA–450 and 731–TA–1122 (Second Review) (Laminated Woven Sacks from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by August 20, 2019.

6. Vote on Inv. No. 731–TA–1123 (Second Review) (Steel Wire Garment Hangers from China). The Commission is currently scheduled to complete and file its determination and views of the Commission by August 22, 2019.

7. Vote on Inv. No. 731–TA–749 (Fourth Review) (Persulfates from China). The Commission is currently scheduled to complete and file its determination and views of the Commission by August 15, 2019.

8. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). 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: July 22, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–15878 Filed 7–23–19; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1008 (Remand)]

Certain Carbon Spine Board, Cervical Collar, CPR Masks and Various Medical Training Manikin Devices, and Trademarks, Copyrights of Product Catalogues, Product Inserts and Components Thereof; Issuance of a Limited Exclusion Order Against Respondents Found in Default; Issuance of a Cease and Desist Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has issued a limited exclusion order (''LEO'') against certain products of eleven respondents found in default. The Commission has also issued a cease and desist order (''CDO'') against respondent Basic Medical Supply, LLC. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5468. 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 (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 24, 2016, based on an amended complaint, as supplemented, filed by Laerdal Medical Corp. of Wappingers Falls, New York, and Laerdal Medical AS of Stavanger, Norway (together, ''Laerdal''). 81 FR 41349–50. The investigation was instituted to determine whether there is a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain carbon spine board, cervical collar, CPR masks, various medical training manikin devices, trademarks, copyrights of product catalogues and product inserts, and components thereof by reason of infringement of one or more of U.S. Patent No. 6,090,058 (''the '058 patent''), U.S. Trademark Registration No. 3,476,656 (''the '656 trademark''), U.S. Copyright Registration Nos. VA 1–879–023 and VA 1–879–026, or by reason of trade dress misappropriation and infringement. *Id.* at 41349. The Commission's notice of investigation named as respondents Shanghai Evenk International Trading Co., Ltd., Shanghai Honglian Medical Instrument Development Co., Ltd., and Shanghai Jolly Medical Education Co., Ltd., all of Shanghai, China; Zhangjiagang Xiehe Medical Apparatus & Instruments Co., Ltd., Zhangjiagang New Fellow Med Co., Ltd., Jiangsu Yongxin Medical Equipment Co., Ltd., and Jiangsu Yongxin Medical-Use Facilities Making, Co., Ltd, all of Zhangjiagang City, China; Jiangyin Everise Medical Devices Co., Ltd., of Jiangyin City, China; Medsource International Co., Ltd. and Medsource Factory, Inc. of PuDong, China; and Basic Medical Supply, LLC of Richmond, Texas (collectively, ''Respondents''). *Id.* at 41350. The Office of Unfair Import Investigations was also named as a party. *Id.*

On November 21, 2016, the ALJ issued an initial determination finding all of the Respondents in default for failing to respond to the complaint and notice of investigation, Order No. 6 (Nov. 21, 2016). The Commission declined to review that determination, Notice (Dec. 20, 2016). The Commission determined to issue an LEO and a CDO with respect to the '058 patent and the '656 trademark, but declined to issue any relief with respect to Laerdal's trade dress or copyright claims. Comm'n Op. (Jun. 14, 2017). The Commission found that, even when the facts in Laerdal's complaint were taken as true, Laerdal's trade dress allegations were inadequate because Laerdal failed to specify its trade dresses, failed to show that its trade dress was nonfunctional, and failed to allege an adequate injury. *Id.* at 8–11. The Commission also found that Laerdal's copyright allegations were legally erroneous. *Id.* at 5–8.

Laerdal appealed the Commission's denial of trade dress relief. On December 7, 2018, the Federal Circuit held that the Commission erred by refusing to issue trade dress relief based on the allegations in the amended complaint, and remanded the proceeding to the Commission for a determination on the proper trade dress remedy and the public interest. *Laerdal Med. Corp.* v. *Int'l Trade Comm'n,* 910 F.3d 1207, 1210, 1216 (Fed. Cir. 2018). The Court's mandate issued on January 29, 2019.

On March 26, 2019, the Commission ordered Laerdal and OUII to: (1) Define each trade dress at issue; (2) explain what remedy is appropriate for each trade dress; (3) explain the effect of each remedy on the public interest; and (4) provide proposed remedial orders. Order (Mar. 26, 2019). Laerdal and OUII each provided responses on April 15, 2019, and reply submissions on April 29, 2019. On April 30, 2019, Laerdal provided corrected versions of its proposed LEO and CDO. The submissions agreed that the appropriate remedy is the entry of an LEO against Respondents and the entry of a CDO against Basic Medical Supply, LLC (''Basic Medical''), that the public interest factors do not weigh against granting these remedial orders, and that bonding should be set at 100 percent of the entered value of the infringing products.

The Commission has determined that the appropriate form of relief in this investigation is: (a) An LEO against Respondents prohibiting the unlicensed entry of products that infringe Laerdal's trade dresses; and (b) an order that Basic Medical cease and desist from importing, selling, offering for sale, marketing, advertising, distributing, offering for sale, transferring (except for exportation), or soliciting U.S. agents or distributors of imported cervical collars that infringe Laerdal's trade dresses. The Commission has further determined that the public interest factors enumerated in section 337(g)(1) (19 U.S.C. 1337(g)(1)) do not preclude the issuance of the LEO and CDO. Finally, the Commission has determined that the bond for importation during the period of Presidential review shall be in the amount of 100 percent of the entered value of the imported subject articles of the respondents. The investigation is terminated.

The Commission's orders and opinion were delivered to the President and the United States Trade Representative on the day of their issuance.

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: July 22, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–15801 Filed 7–24–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–626 and 731–TA–1452–1454 (Preliminary)]

Certain Collated Steel Staples From China, Korea, and Taiwan; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of certain collated steel staples (''CCS staples'') from China, provided for in subheading 8305.20.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.[2] [3] The Commission further determines that imports of CCS staples from Korea and Taiwan that are alleged to be sold in the United States at LTFV are negligible pursuant to section 771(24) of the Act, and its antidumping duty investigations with regard to CCS staples from Korea and Taiwan are thereby terminated pursuant to section 703(a)(1) of the Act.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations with respect to imports of CCS staples from China. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Any parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On June 6, 2019, Kyocera Senco Industrial Tools, Inc. (''Senco''), Cincinnati, Ohio, filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of CCS staples from China and LTFV imports of CCS staples from China, Korea, and Taiwan. Accordingly, effective June 6, 2019, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701–TA–626 and antidumping duty investigation Nos. 731–TA–1452–1454 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 14, 2019 (84 FR 27803). The conference was held in Washington, DC, on June 27, 2019, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on July 22, 2019. The views of the Commission are contained in USITC Publication 4939 (July 2019), entitled *Certain Collated Steel Staples from China, Korea, and Taiwan: Investigation Nos. 701–TA–626 and 731–TA–1452–1454 (Preliminary).*

By order of the Commission.

Issued: July 22, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–15830 Filed 7–24–19; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–19–028]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: July 30, 2019 at 9:30 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–405–406 and 408 and 731–TA–899–901 and 906–908 (Third Review) (Hot-Rolled Carbon Steel Flat Products from China, India, Indonesia, Taiwan, Thailand, and Ukraine). The Commission is currently scheduled to complete and file its determinations and views of the Commission by August 13, 2019.
5. *Outstanding action jackets:* None.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). 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: July 22, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019–15881 Filed 7–23–19; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1153]

Certain Bone Cements, Components Thereof and Products Containing the Same; Commission Determination Not To Review an Initial Determination Granting Complainants' Renewed Motion for Leave To Amend the First Amended Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] *Certain Collated Steel Staples From the People's Republic of China: Initiation of Countervailing Duty Investigation,* 84 FR 31840, July 3, 2019. *Certain Collated Steel Staples From the People's Republic of China, the Republic of Korea, and Taiwan: Initiation of Less-Than-Fair-Value Investigations,* 84 FR 31833, July 3, 2019.

[3] Commissioner Jason E. Kearns did not participate in these investigations.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 18) of the presiding Administrative Law Judge (''ALJ'') granting complainants' renewed motion for leave to amend the first amended complaint and notice of investigation.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3115. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 10, 2019, based on a complaint filed by Heraeus Medical LLC of Yardley, Pennsylvania, and Heraeus Medical GmbH of Wehrheim, Germany (collectively, ''Heraeus''). 84 FR 14394–95 (Apr. 10, 2019). The complaint alleges a violation of section 337 by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States or to prevent the establishment of such an industry. The complaint named as respondents Zimmer Biomet Holdings, Inc. of Warsaw, Indiana; Biomet, Inc. of Warsaw, Indiana; Zimmer Orthopaedic Surgical Products, Inc. of Dover, Ohio; Zimmer Surgical, Inc. of Dover, Ohio; Biomet France S.A.R.L. of Valence, France; Biomet Deutschland GmbH of Berlin, Germany; Zimmer Biomet Deutschland GmbH of Freiburg im Breisgau, Germany; Biomet Europe B.V. of Dordrecht, Netherlands; Biomet Global Supply Chain Center B.V. of Dordrecht, Netherlands; Zimmer Biomet Nederland B.V. of Dordrecht, Netherlands; Biomet Orthopedics, LLC of Warsaw, Indiana; and Biomet Orthopaedics Switzerland GmbH of Dietikon, Switzerland. The Commission's Office of Unfair Import Investigations (''OUII'') was named as a party. Subsequently, the investigation was terminated as to respondents Zimmer Orthopaedic Surgical Products, Inc. and Biomet Europe B.V. Order No. 10 (May 23, 2019), unreviewed Notice (June 14, 2019).

On June 17, 2019, complainants Heraeus moved for leave to amend the first amended complaint and notice of investigation to add three entities as respondents: Zimmer US, Inc. of Warsaw, Indiana; Zimmer, GmbH of Winterthur, Switzerland; and Biomet Manufacturing, LLC of Warsaw, Indiana. On June 21, 2019, respondents Zimmer Biomet Holdings, Inc.; Biomet, Inc.; Zimmer Surgical, Inc.; Biomet France S.A.R.L.; Biomet Deutschland GmbH; Zimmer Biomet Deutschland GmbH; Biomet Global Supply Chain Center B.V.; Zimmer Biomet Nederland B.V.; Biomet Orthopedics, LLC; and Biomet Orthopaedics Switzerland GmbH (collectively, ''Biomet'') filed a response not opposing the motion to add the three entities. On June 25, 2019, OUII also filed a response supporting the motion.

On June 26, 2019, the ALJ issued the subject ID Commission Rule 210.14(b)(1) (19 CFR 210.14(b)(1)), granting the motion. The ALJ found that respondents' motion complies with the Commission's rules. ID at 2. The ALJ also found that there is no dispute over Heraeus's claim that it did not know nor should have known of the three entities' roles in the sale for importation, importation, and/or sale after importation of the accused products in this investigation prior to Biomet's discovery responses. *Id.* at 2–3. The ALJ found that such a circumstance constitutes the requisite good cause. *Id.* at 3. The ALJ further found that the certificate of service appended to Heraeus's motion indicates the three entities were served with the motion in accordance with Commission Rule 210.14(b) (19 CFR 210.14(b)). *Id.* (citing Mot. Mem. at 12.) The ALJ also found no prejudice to the public interest or to the rights of the parties to the investigation would result from granting the motion. *Id.* No party petitioned for review of the ID.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: July 19, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–15760 Filed 7–24–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1103–NEW]

Agency Information Collection Activities: New Information Collection Instrument

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The purpose of this notice is to allow for 30 days for public comment August 26, 2019.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Lashon M. Hilliard, Department of Justice Office of Community Oriented Policing Services, 145 N Street NE, Washington, DC 20530, (202) 514–6563.

Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New Information Collection Instrument.

(2) *Title of the Form/Collection:* Developing and Validating Self-Guided Wellness and Stress Management Tools for Law Enforcement Agencies.

(3) *The agency form number 1103–****.* U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond as well as a brief abstract:*

Primary: Law Enforcement Agencies and community partners.

Abstract: The study proposes an innovative and methodologically sophisticated research design to address the critical issue of law enforcement officer health and wellness.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* The estimate of the data collection tasks for respondents assigned to four groups for a total of 1,550 respondents and anticipated at 45 minutes per respondent.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated time burden is 893 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Room 3E, Room 405A, Washington, DC 20530.

Dated: July 22, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–15832 Filed 7–24–19; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; National Agricultural Workers Survey

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL's) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''National Agricultural Workers Survey.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by September 23, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Mr. Daniel Carroll by telephone at 202–693–2795 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *carroll.daniel.j@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Policy Development and Research, Room N–5641, 200 Constitution Ave. NW, Washington, DC 20210; by email: *carroll.daniel.j@dol.gov;* or by Fax 202–693–2766.

FOR FURTHER INFORMATION CONTACT: Mr. Wayne Gordon by telephone at 202–693–3179 (this is not a toll-free number) or by email at *gordon.wayne@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The National Agricultural Workers Survey (NAWS) is an employment-based, annual survey of the demographic, employment, and health characteristics of hired crop workers, including those who employers hire indirectly through labor contractors. The survey began in 1988. Each year the NAWS contractor interviews between 1,500 and 3,500 crop workers. The contractor interviews crop workers three times per year to account for the seasonality of agricultural employment. ETA uses NAWS data to estimate each state's share of crop workers who are eligible for employment and training services through ETA's National Farmworker Jobs Program. Other Federal agencies similarly use the survey's data to estimate the number and characteristics of crop workers and their dependents who qualify to participate in or receive services from various migrant and seasonal farmworker programs. The United States Department of Agriculture routinely uses NAWS data, along with other data, to estimate changes in agricultural productivity. ETA is seeking approval to continue the NAWS, without change. The Wagner-Peyser Act, as amended (29 U.S.C. 49f (d) and 49*l*–2(a)) authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. To receive consideration, you must provide written comments, which DOL will summarize and include in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control No. 1205–0453.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
• Enhance the quality, utility, and clarity of the information to be collected; and
• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.
Type of Review: Extension without Changes.
Title of Collection: National Agricultural Workers Survey.
Form: Primary Questionnaire.
OMB Control Number: 1205–0453.
Affected Public: Individuals, Farms.
Estimated Number of Respondents: 6,090.
Frequency: Annual.
Total Estimated Annual Responses: 6,090.
Estimated Average Time per Response: 45 minutes.
Estimated Total Annual Burden Hours: 1,615 hours.
Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Molly E. Conway,

Acting Assistant Secretary for Employment and Training.

[FR Doc. 2019–15814 Filed 7–24–19; 8:45 am]

BILLING CODE 4510–FM–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2013–0012]

Modification to the List of Appropriate NRTL Program Test Standards

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the final decision to add a new test standard to the Nationally Recognized Testing Laboratories (NRTL) Program's list of appropriate test standards.

DATES: The actions contained in this notice will become effective on July 25, 2019.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration; telephone: (202) 693–2110 or email: *robinson.kevin@dol.gov.* OSHA's website includes information about the NRTL Program (see *http://www.osha.gov/dts/otpca/nrtl/index.html).*

SUPPLEMENTARY INFORMATION:

I. Background

The NRTL Program recognizes organizations that provide product-safety testing and certification services to manufacturers. These organizations perform testing and certification for purposes of the program, to U.S. consensus-based product-safety test standards. The products covered by the NRTL Program consist of those items for which OSHA safety standards require ''certification'' by a NRTL. The requirements affect electrical products and 38 other types of products. OSHA does not develop or issue these test standards, but generally relies on standards development organizations (SDOs), which develop and maintain the standards using a method that provides input and consideration of views of industry groups, experts, users, consumers, governmental authorities and others having broad experience in the safety field involved.

Addition of New Test Standards to the NRTL Program List of Appropriate Test Standards

Periodically, OSHA will add new test standards to the NRTL list of appropriate test standards following an evaluation of the test standard document. To qualify as an appropriate test standard, the agency evaluates the document to (1) verify it represents a product category for which OSHA requires certification by a NRTL, (2) verify the document represents an end product and not a component, and (3) verify the document defines safety test specifications (not installation or operational performance specifications). OSHA becomes aware of new test standards through various avenues. For example, OSHA may become aware of new test standards by: (1) Monitoring notifications issued by certain SDOs; (2) reviewing applications by NRTLs or applicants seeking recognition to include a new test standard in their scopes of recognition; and (3) obtaining notification from manufacturers, manufacturing organizations, government agencies, or other parties that a new test standard may be appropriate to add to the list of appropriate standards. OSHA may determine to include a new test standard in the list, for example, if the test standard is for a particular type of product that another test standard also covers, addresses a type of product that no standard previously covered, or is otherwise new to the NRTL Program.

Proposed Modification to the NRTL Program List of Appropriate NRTL Program Test Standards

In a March 14, 2019, **Federal Register** notice (84 FR 9384, referred to in this notice as ''Proposed Modification,'' and available at *www.regulations.gov* under Docket ID OSHA–2013–0012–0019), OSHA proposed adding one standard to the NRTL Program List of Appropriate Test Standards. OSHA received one comment on this proposed action (available at *www.regulations.gov* under Docket IDs OSHA–2013–0012–0022). OSHA fully considered this comment and determined that no action was necessary.

II. Final Decision To Add a New Test Standard to the NRTL Program List of Appropriate Test Standards

In this notice, OSHA announces the final decision to add one new test standard, to the NRTL Program List of Appropriate Test Standards, as described in Table 1:

TABLE 1—TEST STANDARDS OSHA DECIDED TO ADD TO THE NRTL PROGRAM LIST OF APPROPRIATE TEST STANDARDS

Test standard	Test standard title
ANSI/CPLSO 14–2016 ...	Crane Insulators.

OSHA will add this test standard to the ''Appropriate Test Standards'' web page on OSHA's website. Access to this web page is available at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

III. Authority and Signature

Loren Sweatt, Acting Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice. Accordingly, the agency is issuing this notice

pursuant to 29 U.S.C. 657(g)(2)), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on July 19, 2019.

Loren Sweatt,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–15812 Filed 7–24–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2013–0002]

Walking and Working Surfaces Standard for General Industry; Extension of the Office of Management and Budget's (OMB) Approval of the Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements contained in the Walking and Working Surfaces Standard for General Industry.

DATES: Comments must be submitted (postmarked, sent, or received) by September 23, 2019.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2013–0002, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the OSHA Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2013–0002) for the Information Collection Request (ICR). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may contact Theda Kenney at the phone number below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of a continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the extent possible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

The collection of information contained in the Walking and Working Surfaces Standard for General Industry is necessary to protect workers from slip, trip, and fall hazards; increases compliance flexibility for employers; incorporates advances in industry best practices, national consensus standards, and technology since OSHA adopted the standard in 1971; and provides greater consistency between subpart D and construction standards. The following describes the information collection requirements in subpart D.

Paragraph 1910.23(b)(10) requires that the employer ensure that any ladder with structural or other defects be immediately tagged with ''Dangerous: Do Not Use'' or with similar language in accordance with § 1910.145 and removed from service until ''repaired . . . or replaced.'' The information will alert employers and workers that the ladder is not safe and must not be used.

Paragraph 1910.27(b)(1)(i) requires that before any rope descent system is used, the building owner inform the employer in writing that the building owner has identified, tested, certified, and maintained each anchorage so it is capable of supporting at least 5,000 pounds (268 kg), in any direction for each employee attached. The information must be based on an annual inspection by a qualified person and certification of each anchorage by a qualified person, as necessary, and at least every 10 years. The information will assure employers and workers that the building owner has inspected, tested and certified the anchorage, which the employer may not own or have any control over, as safe to use. Paragraph 1910.27(b)(1)(ii) requires that the employer ensure that no employee uses any anchorage before the employer has obtained written information from the building owner indicating that each anchorage meets the requirements of § 1910.27(b)(1)(i). The employer must keep the information for the duration of the job. The information will assure employers and workers that the anchorage, which the employer may not own or have any control over, is safe to use.

Paragraph 1910.28(b)(1)(ii) that requires when the employer can demonstrate that it is not feasible or creates a greater hazard to use guardrail, safety net, or personal fall protection systems on residential roofs, the employer must develop and implement a fall protection plan that meets the requirements of 29 CFR 1926.502(k) and training that meets the requirements of 29 CFR 1926.503(a) and (c).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend approval of the information collection requirements contained in the Walking and Working Surfaces Standard for General Industry (29 CFR part 1910, subpart D). OSHA is requesting an adjustment decrease in the burden hours from 498,803 hours to 498,640 hours, a difference of 163 hours. The decrease is due to the change in the methodology of the calculations. The agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Walking and Working Surfaces for General Industry (29 CFR 1910, subpart D).

OMB Control Number: 1218–0199.

Affected Public: Business or other for-profits; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 487,500.

Frequency of Response: On occasion.

Average Time per Response: Various.

Estimated Total Burden Hours: 498,640 hours.

Estimated Cost (Operation and Maintenance): $54,697,500.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2013–0002). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Acting Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on July 19, 2019.

Loren Sweatt,

Acting Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–15813 Filed 7–24–19; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Submission for OMB Review, Comment Request, Proposed Collection: Museums for Digital Learning Program Evaluation

AGENCY: Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

ACTION: Submission for OMB Review, Comment Request.

SUMMARY: The Institute of Museum and Library Services announces the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. By this notice, IMLS is soliciting comments concerning the forms and instructions for the program evaluation for the Museums for Digital Learning (MDL) Project for the next three years.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Comments must be submitted to the office listed in the **FOR FURTHER INFORMATION CONTACT** section below on or before August 25, 2019.

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses).

ADDRESSES: Comments should be sent to Office of Information and Regulatory Affairs, *Attn.:* OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395–7316.

FOR FURTHER INFORMATION CONTACT: Dr. Sandra Webb, Director of Grant Policy and Management, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Dr. Webb can be reached by Telephone: 202–653–4718 Fax: 202–653–4608, or by email at *swebb@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. Our vision is a nation where museums and libraries work together to transform the lives of individuals and communities. To learn more, visit *www.imls.gov.*

Current Actions: The *Museums for Digital Learning* (MDL) is a project funded by the Institute of Museum and Library Services (IMLS) that seeks to identify and test new ways that digitized museum collections can be made available in the form of engaging digital educational resources via a pilot digital platform to educators around the country seeking to engage their students with all subjects. This two-year project is being led by the Indianapolis Museum of Art at Newfields in collaboration with two museum content partners—The Field Museum and History Colorado and a team of K–12 educators. Once the pilot suite of online products has been created by the project team, they will be tested in the classrooms of the ten educational partners. Testing and validation of the content contribution approach and standard templates to the pilot platform will be conducted with a cohort of up to ten additional museums of various sizes and disciplines.

This project aligns with IMLS's strategic goal and priorities of building the digital capacity of the sector. MDL will catalyze and empower museums to come together and create a national model with a shared vision to thoughtfully assess some of the critical gaps in the current platforms and digital access/use models, and then leverage the power of a shared digital platform to provide easy-to-access, interdisciplinary, and dynamic content from museums in digital format for educators and students.

The project will benefit the national education sector by providing a model for museums to collaborate as a sector with educators and engaging them not just as users of museum content and services, but as co-creators and co-facilitators of student learning; a suite of curriculum enhancing and student-centric digital collections-based educational resources; and an opportunity to pilot-test and improve the resources from the formative evaluation to better meet the needs of the nation's learners.

The product and process evaluation of the MDL project will be completed by a third party evaluator with experience in evaluating digital education platforms produced by the cultural heritage community. The process evaluation aspect will assess the overall planning and implementation of the collaborative model of MDL between the partner museums and the educators, as well as the effectiveness of the training and ease of content contribution of the ten additional museums. Much of the front-end and user experience design of the MDL platform will be formed through the collaboration and co-creation process between the cooperator, lead museum content partners, and the team of educators. The product evaluation will assess the ease of access and educational value of the collections-based digital education products for educators and students.

This action is to create the overall evaluation plan, survey and data collection instruments and instructions for the various evaluation techniques to be used at different points in the development and implementation of the MDL pilot initiative for the next two years.

Agency: Institute of Museum and Library Services.

Title: Museums for Digital Learning Project Evaluation.

OMB Number: 3137–TBD.

Frequency: Once.

Affected Public: Museum staff, teachers.

Number of Respondents: 100.

Estimated Average Burden per Response: 45 minutes.

Estimated Total Annual Burden: 65 hours.

Total Annualized capital/startup costs: N/A.

Total Annual costs: $1,755.

Dated: July 22, 2019.

Kim Miller,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2019–15800 Filed 7–24–19; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Mathematical and Physical Sciences (#66)—(Virtual Meeting).

Date and Time: August 23, 2019; 1:00 p.m. to 4:00 p.m.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

Type of Meeting: Open.

Contact Person: Nadège Aoki, National Science Foundation, 2415 Eisenhower Avenue, Room C 9015B, Alexandria, Virginia 22314; Telephone: 703/292–4934.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to MPS programs and activities.

Agenda

Friday, August 23, 1:00 p.m. to 4:00 p.m.

- Presentation: PFC Report presentation, Donald Geesaman
- Discussion: PFC Report
- Presentation: PHY COV Report presentation
- Discussion: PHY COV Report
- Discussion: Other current updates

Dated: July 19, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–15781 Filed 7–24–19; 8:45 am]

BILLING CODE 7555–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Notices Under Section 4062(e) of ERISA

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act, a collection of information that is necessary to fulfill various reporting obligations following a cessation of operations at a facility. This notice informs the public of PBGC's

request and solicits public comment on the collection.

DATES: Comments must be submitted by August 26, 2019.

ADDRESSES: Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, via electronic mail at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974.

A copy of the request will be posted on PBGC's website at: *https://www.pbgc.gov/prac/laws-and-regulations/information-collections-under-omb-review.* It may also be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel, 1200 K Street NW, Washington, DC 20005–4026; faxing a request to 202–326–4042; or, calling 202–326–4040 during normal business hours (TTY users may call the Federal Relay Service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040). The Disclosure Division will email, fax, or mail the information to you, as you request.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–326–4400, extension 6563; or Erika E. Barnes (*barnes.erika@pbgc.gov*), Assistant General Counsel, Bankruptcy, Transactions, and Terminations Department, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–326–4400, extension 3460. TTY users may call the Federal Relay Service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400, extension 6563.

SUPPLEMENTARY INFORMATION: Section 4062(e) of the Employee Retirement Income Security Act of 1974 (ERISA) imposes reporting obligations in the event of a ''substantial cessation of operations.'' A substantial cessation of operations occurs when a permanent cessation at a facility causes a separation from employment of more than 15 percent of all ''eligible employees.'' ''Eligible employees'' are employees eligible to participate in any of the facility's employer's employee pension benefit plans. Following a substantial cessation of operations, the facility's employer is treated, with respect to its single employer pension plans covered by title IV of ERISA that are covering participants at the facility, as if the employer were a withdrawing substantial employer under a multiple-employer plan. Under section 4063(a) of ERISA, the Pension Benefit Guaranty Corporation (PBGC) must receive notice of the substantial cessation of operations and a request to determine the employer's resulting liability.

To fulfill such resulting liability, the employer may elect, under section 4062(e)(4)(A), to make additional contributions annually for seven years to plans covering participants at the facility where the substantial cessation of operations took place. Under sections 4062(e)(4)(E)(i)(I), (II), (III), (IV), and (V) respectively, an employer that is making the election for annual additional contributions must give notice to PBGC of: (1) Its decision to make the election, (2) its payment of an annual additional contribution, (3) its failure to pay an annual additional contribution, (4) its receipt of a funding waiver from the Internal Revenue Service (''IRS''), and (5) the ending of its obligation to make annual additional contributions.

PBGC is proposing a new form series that would be used to fulfill these reporting obligations. An employer or a plan administrator would file Form 4062(e)–01 to notify PBGC of the occurrence of a substantial cessation of operations and request a determination of the employer's liability. An employer would file Form 4062(e)–02 to notify PBGC that it made the election to pay annual additional contributions to a plan. An employer would file Form 4062(e)–03 to notify PBGC that it paid an annual additional contribution, received a funding waiver from the IRS, or is no longer obligated to pay annual additional contributions. Finally, an employer would file Form 4062(e)–04 to notify PBGC that it failed to pay an annual additional contribution to the plan.

PBGC needs the requested information in the forms and notification (1) to determine an employer's liability to a plan following a substantial cessation of operations and (2) to ensure that an employer that made the election of annual additional contributions is fulfilling its payment obligations.

On May 15, 2019, PBGC published in the **Federal Register** (at 84 FR 21840) a notice informing the public of its intent to request an approval of the new form series. PBGC did not receive any comments about this collection of information.

PBGC is requesting that OMB approve the collection of information for three years. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that 70 forms (10 Forms 4062(e)–01, 10 Forms 4062(e)–02, 49 Forms 4062(e)–03, and one Form 4062(e)–04) would be submitted each year. PBGC estimates that these forms would be completed by a combination of plan office staff and outside professionals (attorneys and actuaries). PBGC estimates a total annual hour burden of 315 hours (based on plan office time). The estimated dollar equivalent of this hour burden, based on an assumed hourly rate of $75 for administrative, clerical, and supervisory time is $23,625. PBGC estimates a total annual cost burden of $92,750 (based on 265 professional hours assuming an average hourly rate of $350).

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2019–15763 Filed 7–24–19; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–169 and CP2019–191; MC2019–170 and CP2019–192]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 29, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the

Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–169 and CP2019–191; *Filing Title:* USPS Request to Add First-Class Package Service Contract 100 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* July 29, 2019.

2. *Docket No(s).:* MC2019–170 and CP2019–192; *Filing Title:* USPS Request to Add Priority Mail Contract 539 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 19, 2019; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Kenneth R. Moeller; *Comments Due:* July 29, 2019.

This Notice will be published in the **Federal Register**.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2019–15838 Filed 7–24–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86414; File No. SR–NYSEArca–2019–38]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendments No. 1 and No. 2, Regarding Investments of the Aware Ultra-Short Duration Enhanced Income ETF

July 19, 2019.

On May 15, 2019, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] a proposal to change the listing rule applicable to shares of the Aware Ultra-Short Duration Enhanced Income ETF, a series of the Tidal ETF Trust. The proposed rule change was published for comment in the **Federal Register** on June 4, 2019.[4] On July 8, 2019, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and superseded the original filing in its entirety. On July 10, 2019, the Exchange filed Amendment No. 2 to the proposed rule change, which amended the proposed rule change as modified by Amendment No. 1. The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 19, 2019. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposal. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates September 2, 2019, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2019–38), as modified by Amendments No. 1 and No. 2.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15771 Filed 7–24–19; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 85955 (May 29, 2019), 84 FR 25863.

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86413; File No. SR–ICEEU–2019–012]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change, Security-Based Swap Submission or Advance Notice Relating to the ICE Clear Europe Treasury and Banking Services Policy, Liquidity Management Procedures, Investment Management Procedures and Unsecured Credit Limits Procedures

July 19, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 5, 2019, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared by ICE Clear Europe. The Commission is publishing

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change, Security-Based Swap Submission, or Advance Notice

ICE Clear Europe proposes to adopt a new Treasury and Banking Services Policy, new Liquidity Management Procedures and Investment Management Procedures and revised Unsecured Credit Limits Procedures (collectively, the ''Treasury Documents''). (The Investment Management Procedures, Liquidity Management Procedures and Unsecured Credit Limits Procedures are referred to herein as the ''Procedures Documents''.) The Treasury Documents would replace the existing Liquidity Risk Management Framework, Liquidity Plan, Investment Management Policy and Approved Financial Institutions Policy (the ''Existing Documents''). The revisions would not involve any changes to the ICE Clear Europe Clearing Rules or Procedures.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission or Advance Notice

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission or Advance Notice

(a) Purpose

ICE Clear Europe is proposing to adopt the new Treasury Documents in order to:

- Simplify and streamline the documentation;
- remove inaccuracies and unused elements;
- remove elements that are documented or managed elsewhere;
- better separate between policy-level documentation (Policies) and implementation-level documentation (Procedures); and
- improve operational flexibility.

Generally, other than certain additional liquidity review procedures as discussed below, the changes would not alter the existing substantive treasury and banking practices of the Clearing House. Broadly, the proposed amendments would combine the high level policy elements of the Existing Documents into the Treasury and Banking Services Policy. The supporting detail for the policy would be in the new Procedures Documents. Following adoption of the Treasury Documents, the Existing Documents would be retired.

Treasury and Banking Services Policy

The Treasury and Banking Services Policy (the ''Policy'') would set out the overall principles applied to the ICE Clear Europe cash and collateral management functions for Clearing Member (''CM'') assets. The Treasury and Banking Services Policy would replace the existing Liquidity Risk Management Framework and contain policy-level information relating to liquidity risk management and investment management.

a. Treasury and Banking Services

The proposed Policy would state that the treasury and banking services (''TBS'') department is responsible for cash and collateral management functions for CM assets including relating to liquidity and cash margin investment and that these functions are subject to applicable regulations and the Rules and Procedures, particularly the Finance Procedures. The Policy would further outline certain procedures relating to initial margin (''IM''), guaranty fund (''GF'') contributions and variation margin (''VM'') and the manner in which CMs would cover these liabilities.

b. Cash Management

The proposed Policy would address the manner in which ICE Clear Europe transfers cash in the relevant currencies intraday through an Assured Payment System (''APS'') into its 'concentration banks' and invests or secures such cash at end of day. ICE Clear Europe uses multiple APS banks which are approved financial institutions that have committed to meet certain technical and operational requirements. Approved financial institutions are financial service providers that have been approved by the Credit Risk team and meet eligibility and monitoring criteria set out in the Unsecured Credit Limits Procedures.

c. Liquidity Risk

The proposed Policy would describe the sources of liquidity risks and, at a high level, how liquidity shortfalls may be addressed. It would further set out ICE Clear Europe's liquidity risk management objective to maintain sufficient liquid resources in all relevant currencies to meet its payment obligations as they come due and its strategy to achieve this objective. Its strategy would entail structuring and sequencing its cash flows to minimize liquidity risks, monitoring intraday cash inflows and outflows to ensure payments are met, and running daily liquidity stress tests (''LSTs'').

The Policy would set out that ICE Clear Europe runs daily liquidity monitoring and stress testing to: Measure and monitor its liquidity position on an ongoing basis and assess its potential immediate and future liquidity needs across a range of extreme but plausible market scenarios. The LSTs are set out in the LST Model Documentation and would be reviewed periodically as would be set out in the Liquidity Management Procedures. Models underpinning the LSTs would be reviewed in accordance with ICE Clear Europe's Model Risk Governance Framework.

d. Investment of Cash

The proposed Policy would set out ICE Clear Europe's investment management objective to safeguard the principal of its CMs' cash, maintain sufficient liquidity to cover its payment obligations and obtain a reasonable rate of return. Its related strategy would be to: (i) Manage its investment portfolio to ensure it has sufficient liquidity; (ii) rebalance its investment portfolio as a result of the LSTs and available liquidity to ensure enough cash is available to meet daily payment obligations; and (iii) invest or secure cash after the relevant deadline has passed for CMs to withdraw or exchange excess cash. The proposed Policy would set out the criteria to determine whether investment instruments are acceptable, including requiring: (i) That the market for the instruments have sufficient price history and be sufficiently liquid and transparent; and (ii) that the instrument not be issued by a CM or entity that is part of the same group as a CM and not be issued by a CCP or entity providing services critical to ICE Clear Europe's functioning. The proposed Policy would further require that investments are in sufficiently liquid currencies, diversified across counterparties, subject to credit criteria and, with respect to reverse repo collateral, subject

[3] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

to suitable haircuts. Parties and employees involved in the investment process would be required to refrain from conflicts of interest and ICE Clear Europe would be required to keep appropriate records.

e. Collateral Management

Pursuant to the proposed Policy, CMs could substitute cash covering IM or GF requirements with collateral or cash in a different currency, subject to constraints set out in the ICE Clear Europe Finance Procedures. Whenever practicable, ICE Clear Europe would hold accounts with Central Securities Depositories (''CSDs''). Assets of individual CMs and, where appropriate, clients with individually segregated assets, would be required to be readily identifiable in ICE Clear Europe's systems.

f. Governance

The Policy would also address procedures for ensuring that the proposed Treasury Documents remain up-to-date and are reviewed in accordance with ICE Clear Europe's governance processes, as well as for handling exceptions. The policy would also address reporting of material breaches or unapproved deviations from the Policy to the Head of Department, a senior member of the Risk Oversight Department and a senior member of the Compliance Department who would together will determine if further escalation should be made to relevant senior executives, the Board and/or competent authorities.

Liquidity Management Procedures

(i) Proposed Amendments

Pursuant to the proposed amendments, the Liquidity Management Procedures would replace the current Liquidity Plan. The procedures would provide a number of improvements over existing liquidity risk management practices and in particular address the issues described below.

- Pursuant to the proposed amendments, a haircut would be applied to the liquidation value of securities owned outright as part of the LSTs.
- ICE Clear Europe would more clearly and concisely document its liquidity strategy including a clear explanation of how it manages its so-called ''cover 2'' requirements. Further, the LST scenarios would no longer be detailed in the Liquidity Management Procedures but would be moved to LST Model Documentation that can be updated more flexibly as needed.
- The amendments would clarify the distinction between liquidity tools used to address a technical obstacle to making payments and those used to address a default or investment loss.
- Currencies would no longer be distinguished as material or non-material, and instead ICE Clear Europe would look to the size of the relevant obligation for LST purposes.
- The Liquidity Management Procedures would explicitly document ICE Clear Europe's approach to reviewing scenarios and assumptions underlying its LSTs.
- The Liquidity Management Procedures would address settlements and deliveries in more detail including how this is additive to defaulting member exposure and how this risk is managed.
- The Liquidity Management Procedures would explicitly document periodic reviews on a monthly basis, including consideration of emerging risks.
- The Liquidity Management Procedures would establish and document a process for formal governance review and challenge of the assumptions for the hypothetical LST scenarios (*e.g.,* systemic or market infrastructure scenarios), with a link to emerging risks.
- The cover 1 liquidity stress scenario required under Commission rules,[4] based on qualifying liquid resources under such rules, would be referenced in the Liquidity Management Procedures and documented in the LST Model Documentation.
- The procedures would recognize that ICE Clear Europe has determined that 'other prearranged funding arrangements' are highly reliable even in extreme but plausible market conditions.
- The procedures would memorialize the process of conducting comprehensive periodic reviews to evaluate LSTs and stress scenarios.

(ii) Summary of Other Aspects of Liquidity Management Procedures

(A) Overview

The proposed Liquidity Management Procedures would generally set out how ICE Clear Europe would address:

- Monitoring and management of liquidity risks, liquidity needs and liquidity resources; and
- Access to liquidity resources, including in case of liquidity shortfalls.

The procedures would be structured to address:

- ICE Clear Europe's payment obligations;
- Management and monitoring of ICE Clear Europe's liquidity needs and maintenance of sufficient liquid resources;
- Daily assessment and valuation of liquid assets;
- Sources and mitigations of liquidity risk; timescales of liquid resources;
- Substitution of cash with non-cash collateral and withdrawal of excess margin by CMs;
- Liquidity shortfalls;
- Replenishment of liquidity in stress events;
- Periodic reviews of liquidity stress tests and liquidity providers; and
- Governance, breach management and exception handling (in the same manner as under the Policy).

(B) Payment Obligations

This section of the proposed procedures would set out the sources of payment obligations relevant to liquidity management, which are: (i) Paying VM to those with positive P&L on their trades, (ii) paying delivery or settlement monies when trades deliver or settle; and (iii) returning surplus IM or other margin to individual CMs. ICE Clear Europe would only have a liquidity need not covered in the ordinary course where there has been a firm default or a technical issue at a financial services provider. The proposed procedures would explain the various structural arrangements that ICE Clear Europe has in place to minimize liquidity risk.

(C) Management and Monitoring of Liquidity Needs

The proposed procedures would explain that ICE Clear Europe runs a range of LSTs each day as set out in the LST Model Documentation, which covers CM default scenarios as well as defaults of financial service providers and defaults with other operational outflows. The Clearing Risk team develops market scenarios and calculates stress losses to set the required levels of IM and GF for CMs and accounts which the TBS department then aggregates across different operational scenarios to set the level of liquid resources ICE Clear Europe must maintain. Potential investment losses are also calculated should the defaulting CMs also be investment counterparties, as well as cash outflows due to deliveries and settlements. Throughout the day, the TBS department monitors outstanding payment requests to identify failures which could lead to default using exception-based monitoring tools, as well as the current level of available liquid resources compared to the level needed within currency and maturity buckets.

[4] 17 CFR 240.17Ad–22(e)(7).

(D) Sources and Mitigation of Liquidity Risk

The proposed procedures would list specific sources of default liquidity risk, and the means through which ICE Clear Europe generally manages such risks.

(E) Timescale of Liquidity Resources

The proposed procedures note that for liquidity management monitoring, ICE Clear Europe would only include resources that can be drawn upon on a same day basis, including cash, investments maturing that day, sovereigns with different maturities that can be liquidated that day, highly reliable uncommitted operating lines and committed repo lines. Treasuries held as collateral against reverse repo agreements have been determined to be highly reliable, even in extreme but plausible market conditions, because ICE Clear Europe would only accept those of high credit quality and subject them to haircuts in its LSTs which were developed, including stressed market conditions.

(F) Liquidity Shortfalls

The proposed procedures would describe how in a default situation, liquidity is generated through the default management waterfall and ICE Clear Europe could use its existing pool of cash first to cover payment obligations as this may be more readily available. In a liquidity shortfall situation due to a technical issue, ICE Clear Europe could use its uncommitted and committed lines or liquidate non-cash collateral.

(G) Replenishment of Liquidity in Stress Events

The procedures would explain that with respect to replenishment, provided losses would be covered by the default waterfall, (i) if the losses were covered by the margin and GF contribution of the defaulting CM, there would be no need for replenishment, and (ii) if part of the GF contributions of the other CMs or ICE Clear Europe's GF contribution were used, then after contribution requirements are reassessed, they would be replenished as set out in the Rules. Where additional liquidity would be required due to a technical issue, it would automatically be remedied upon resolution of the issue as it would involve no overall reduction in liquidity resources.

(H) Liquidity Stress Tests

The LSTs would assess the impact on sources of liquidity and liquidity exposures in both currency and time in a broad range of market and operational scenarios. To assess them, the TBS, Clearing Risk and Risk Oversight departments would meet monthly to analyze and discuss: Whether to include any new or emerging risks in the stress tests, the adequacy and assumptions of LST scenarios, the adequacy of stress test inputs, acceptance of current LST scenario calibrations, performance of liquidity providers, annual due diligence reviews of liquidity providers to assess their ability to perform their role as such, and annual testing of sources of liquidity. In stressed market conditions, the TBS, Clearing Risk and Risk Oversight departments would meet more frequently than monthly to ensure LSTs and stress scenarios are fit for purpose. The above analysis of LSTs would be periodically reported to a Board-level committee.

Investment Management Procedures

Pursuant to the proposed amendments, the Investment Management Procedures would contain the procedures-level information from the current Investment Management Policy, setting out the permitted investments when investing or securing cash received from CMs either as GF contributions, IM or other types of margin. The proposed procedures would also set out constraints on these investments, including concentration limits, credit ratings and maturity limits and any additional considerations in times of insufficient market supply of approved investments. The procedures would set out the investment management objective and investment currencies (EUR, GDP, and USD).

With respect to authorized investments in times of normal supply, pursuant to the proposed procedures: (i) Investments could only be made with approved financial institutions; (ii) at least 50% of the portfolio in each currency should be invested in overnight reverse repurchase (''repo'') agreements; (iii) non-overnight investments should have a variety of maturity dates; (iv) customer funds of FCM/BD Clearing Members would be required to be segregated from those of other CMs, to be held in permitted depositories for such customer funds (consistent with applicable regulations) and to be invested only in overnight reverse repos and direct purchases of U.S. sovereign obligations with permitted counterparties for such transactions under applicable regulations; and (v) purchased securities would be required to be held until maturity to minimize market risk impact. The proposed procedures would contain a table setting out the authorized instruments, concentration limits, maximum maturity and minimum credit ratings or allowed entities. The TBS department would monitor adherence to the investment criteria.

The proposed procedures would set out additional considerations for reverse repo agreements requiring: (i) At least four investment counterparties in each currency; (ii) consideration by the Head of the TBS department, or their delegate, in the event of a counterparty downgrade, as to whether it may be more prudent to liquidate or hold a trade until maturity; (iii) deeming repo agreements to have a maturity equal to the schedule repurchase date of the underlying securities, or where the agreement is subject to a demand, the applicable notice period; and (iv) collection of only certain collateral deemed acceptable and subject to a predetermined haircut.

In times of insufficient market supply, U.S. government agency securities and supranational obligations would also be acceptable for investment and repo agreement collateral. Further, ICE Clear Europe would no longer need to invest at least 50% in overnight repurchase agreements and concentration limits would no longer apply. In periods of lower overnight supply, investments should be allocated to other investment types according to the order of preference set out in the procedures.

Breaches of concentration limits would be escalated to the Risk Oversight Department and the Compliance team as well as reported to the relevant regulators through regular reports. The investment portfolio would be rebalanced to return within the concentration limits. The TBS department would, in conjunction with the Risk Oversight Department and Clearing Risk team, review the concentration limits every quarter. The procedures would also address procedure governance, breach management and exception handling (in the same manner as under the Policy).

Unsecured Credit Limits Procedures

The proposed revised Unsecured Credit Limits Procedures would support aspects of the Policy, the Investment Management Procedures and the Counterparty Rating Systems. The amendments to the procedures would address the eligibility requirements for counterparties and monitoring procedures for unsecured exposure.

(i) Eligibility Methodology

The proposed amendments to the procedures would require that in order for a legal entity to be eligible as a counterparty or financial service provider, it would need to be regulated

by a competent authority and comply with the applicable minimum external rating and maximum ICE Clear Europe rating for such entity type as set out in the procedures. If the entity is a repo provider, it would need to be organized in the US or EU countries satisfying the minimum external rating.

(ii) Monitoring

The proposed procedures would require daily monitoring of overnight unsecured exposure at the legal entity level. Subject to data availability and technology, overnight unsecured exposures relative to unsecured limits would also be monitored at least weekly. Other exposures and aggregation with other Legal Entities of the same group of companies would be monitored at least monthly. The procedures would also address procedure governance, breach management and exception handling (in the same manner as under the Policy).

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments are consistent with the requirements of Section 17A of the Act [5] and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(F) of the Act [6] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed Treasury Documents are intended to consolidate and clarify certain existing policies and procedures relating to treasury operations and liquidity management. Except as noted above, the amendments would not generally change existing practices, but in ICE Clear Europe's view the revised documentation would facilitate ongoing treasury risk and liquidity risk management by the Clearing House, so that the Clearing House would be able to meet its short-term financial obligations in the event of clearing member defaults or other liquidity stress events. These processes would therefore promote overall Clearing House risk management and facilitate the prompt and accurate clearing of cleared contracts and protect investors and the public interest in the sound operations of the Clearing House, consistent with the requirements of Section 17A(b)(3)(F).[7] Through facilitating ongoing treasury risk and liquidity risk management that enables the Clearing House to meet its short-term financial obligations in the event of clearing member defaults or other liquidity stress events, the amendments may also enhance the safeguarding of securities and funds in the custody or control of the Clearing House or for which it is responsible.

The proposed Treasury Documents are further consistent with the requirements of Rule 17Ad–22(e)(3)(i) and (ii) [8] through generally strengthening ICE Clear Europe's risk management framework for managing liquidity risks, including setting out in detail how such risks are monitored and managed, and addressing the possibility of recovery should other mechanisms to address liquidity resource shortfalls fail.

The proposed Treasury Documents are also consistent with the requirements of Rule 17Ad–22(e)(7)(i) and (ii) and Rule 17Ad–22(a)(14) [9] which require ICE Clear Europe to maintain sufficient qualifying liquid resources. In compliance with this requirement, the proposed Treasury Documents would document ICE Clear Europe's procedures for holding liquid resources in the relevant currencies to effect same-day settlement payment obligations under a wide range of scenarios. As would be described in the proposed Liquidity Management Procedures, the LST scenarios used to test resources are designed to cover the default of at least the two CMs with the largest exposure to ICE Clear Europe, in extreme but plausible market conditions, together with defaults of financial service providers and other operational outflows. The Liquidity Management Procedures would also expressly address the scenario of the default of the family with the largest aggregate payment obligation for ICE Clear Europe, in extreme but plausible market conditions, as required under Commission Rule 17Ad–22(e)(7).[10] As would be described in the Liquidity Management Procedures, if necessary, ICE Clear Europe has uncommitted FX lines to enable it to make the necessary currency conversions and committed and uncommitted repo facilities to obtain cash from securities positions. It would also apply haircuts to any non-cash collateral or cash in currencies other than required currencies in calculating available liquid resources. The TBS department would monitor liquid resource requirements relative to exposures throughout the day to further ensure that ICE Clear Europe would be able to meet its liquidity requirements. In compliance with the definition of ''qualifying liquid resources,'' the Liquidity Management Procedures would require that ICE Clear Europe only include resources which would be cash or which could be transferred into

[5] 15 U.S.C. 78q–1.

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 17 CFR 240.17Ad–22(e)(3)(i)–(ii). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [m]aintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which:

(i) Includes risk management policies, procedures, and systems designed to identify, measure, monitor, and manage the range of risks that arise in or are borne by the covered clearing agency, that are subject to review on a specified periodic basis and approved by the board of directors annually;

(ii) Includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses;''

[9] 17 CFR 240.17Ad–22(e)(7)(i)–(ii). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [e]ffectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum, doing the following:

(i) Maintaining sufficient liquid resources at the minimum in all relevant currencies to effect same-day and, where appropriate, intraday and multiday settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios that includes, but is not limited to, the default of the participant family that would generate the largest aggregate payment obligation for the covered clearing agency in extreme but plausible market conditions;

(ii) Holding qualifying liquid resources sufficient to meet the minimum liquidity resource requirement under paragraph (e)(7)(i) of this section in each relevant currency for which the covered clearing agency has payment obligations owed to clearing members;

17 CFR 240.17Ad–22(a)(14) Qualifying liquid resources means, for any covered clearing agency, the following, in each relevant currency:

(i) Cash held either at the central bank of issue or at creditworthy commercial banks;

(ii) Assets that are readily available and convertible into cash through prearranged funding arrangements, such as:

(A) Committed arrangements without material adverse change provisions, including:

(1) Lines of credit;

(2) Foreign exchange swaps; and

(3) Repurchase agreements; or

(B) Other prearranged funding arrangements determined to be highly reliable even in extreme but plausible market conditions by the board of directors of the covered clearing agency following a review conducted for this purpose not less than annually; and

(iii) Other assets that are readily available and eligible for pledging to (or conducting other appropriate forms of transactions with) a relevant central bank, if the covered clearing agency has access to routine credit at such central bank in a jurisdiction that permits said pledges or other transactions by the covered clearing agency.

[10] 17 CFR 240.17Ad–22(e)(7).

cash or could be drawn upon on a same day basis, specifically listing appropriate resources. In further compliance with Rule 17Ad–22(e)(5),[11] ICE Clear Europe sets and enforces appropriately conservative haircuts with respect to the assets it accepts as collateral as would be described in the Liquidity Management Procedures.

The Treasury Documents are similarly compliant with Rule 17Ad–22(e)(16)[12] and would require assets be held in a manner that minimizes risk of loss and invested in assets with minimal liquidity risk. The Investment Management Procedures would set out detailed requirements to ensure that investment risks are minimized. Only certain investments would be permitted and they would be subject to constraints such as concentration limits, credit ratings, currencies and maturity limits.

Rules 17Ad–22(e)(7)(iii) and (e)(9)[13] require clearing agencies, where possible, to access accounts and services at a central bank. As would be described in the proposed Treasury Documents, ICE Clear Europe uses central banks for EUR and GBP deposits, and uses highly rated commercial banks as concentration banks for USD to minimize the risk of concentration bank defaults (as it is not eligible to maintain a USD account with the Federal Reserve). Investments are made as soon as possible after the deadline for CM withdrawals or exchanges of margin to further manage custody related risks.

Rule 17Ad–22(e)(7)(iv)[14] requires clearing agencies to undertake due diligence to confirm their liquidity providers have sufficient information to understand the risks and have the capacity to perform their liquidity commitments. As would be described in the proposed Treasury Documents, ICE Clear Europe uses multiple APS banks and ensures that they sign contracts committing to meet certain technical and operational requirements to confirm that these parties understand the risks. They must also be financial service providers that have been approved by the Credit Risk team and meet eligibility, credit limit and monitoring criteria as would be described in the Unsecured Credit Limits Procedures.

In compliance with the liquid resource stress testing requirements of Rule 17Ad–22(e)(7)(vi),[15] as would be described in the proposed Treasury Documents, ICE Clear Europe runs daily liquidity stress testing to measure and monitor its liquidity position and assess the impact on sources of liquidity and liquidity exposures in both currency and time in a broad range of market and operational scenarios. The TBS, Clearing Risk and Risk Oversight departments would meet monthly to assess the tests and more frequently in stressed market conditions. The LSTs are set out in the LST Model Documentation and models underpinning the LSTs would be reviewed in accordance with ICE Clear Europe's Model Risk Governance Framework.

In compliance with Rule 17Ad–22(e)(7)(ix),[16] the proposed Liquidity Management Procedures would set out ICE Clear Europe's process to replenish liquid resources. Provided losses would be covered by the default waterfall, (i) if the losses were covered by the margin and GF contribution of the defaulting CM, there would be no need for replenishment, and (ii) if part of the GF contributions of the other CMs or ICE Clear Europe's GF contribution were used, they would be replenished as set out in the Rules.

Rule 17Ad–22(e)(2)[17] requires that a covered clearing agency provide for governance arrangements that, among other matters, are ''clear and

[11] 17 CFR 240.17Ad–22(e)(5). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [l]imit the assets it accepts as collateral to those with low credit, liquidity, and market risks, and set and enforce appropriately conservative haircuts and concentration limits if the covered clearing agency requires collateral to manage its or its participants' credit exposure; and require a review of the sufficiency of its collateral haircuts and concentration limits to be performed not less than annually.''

[12] 17 CFR 240.17Ad–22(e)(16). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [s]afeguard the covered clearing agency's own and its participants' assets, minimize the risk of loss and delay in access to these assets, and invest such assets in instruments with minimal credit, market, and liquidity risks.''

[13] 17 CFR 240.17Ad–22(e)(7)(iii). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [e]ffectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum, doing the following:

(iii) Using the access to accounts and services at a Federal Reserve Bank, pursuant to Section 806(a) of the Payment, Clearing, and Settlement Supervision Act of 2010 (12 U.S.C. 5465(a)), or other relevant central bank, when available and where determined to be practical by the board of directors of the covered clearing agency, to enhance its management of liquidity risk;'' maintain and enforce written policies and procedures reasonably designed to, as applicable: [c]onduct its money settlements in central bank money, where available and determined to be practical by the board of directors of the covered clearing agency, and minimize and manage credit and liquidity risk arising from conducting its money settlements in commercial bank money if central bank money is not used by the covered clearing agency.''

[14] 17 CFR 240.17Ad–22(e)(7)(iv). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [e]ffectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum, doing the following:

(iv) Undertaking due diligence to confirm that it has a reasonable basis to believe each of its liquidity providers, whether or not such liquidity provider is a clearing member, has:

(A) Sufficient information to understand and manage the liquidity provider's liquidity risks; and

(B) The capacity to perform as required under its commitments to provide liquidity to the covered clearing agency;

[15] 17 CFR 240.17Ad–22(e)(7)(vi). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [e]ffectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum, doing the following:

(vi) Determining the amount and regularly testing the sufficiency of the liquid resources held for purposes of meeting the minimum liquid resource requirement under paragraph (e)(7)(i) of this section by, at a minimum:

(A) Conducting stress testing of its liquidity resources at least once each day using standard and predetermined parameters and assumptions;

(B) Conducting a comprehensive analysis on at least a monthly basis of the existing stress testing scenarios, models, and underlying parameters and assumptions used in evaluating liquidity needs and resources, and considering modifications to ensure they are appropriate for determining the clearing agency's identified liquidity needs and resources in light of current and evolving market conditions;

(C) Conducting a comprehensive analysis of the scenarios, models, and underlying parameters and assumptions used in evaluating liquidity needs and resources more frequently than monthly when the products cleared or markets served display high volatility or become less liquid, when the size or concentration of positions held by the clearing agency's participants increases significantly, or in other appropriate circumstances described in such policies and procedures; and

(D) Reporting the results of its analyses under paragraphs (e)(7)(vi)(B) and (C) of this section to appropriate decision makers at the covered clearing agency, including but not limited to, its risk management committee or board of directors, and using these results to evaluate the adequacy of and adjust its liquidity risk management methodology, model parameters, and any other relevant aspects of its liquidity risk management framework;''

[16] 17 CFR 240.17Ad–22(e)(7)(ix). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: [e]ffectively measure, monitor, and manage the liquidity risk that arises in or is borne by the covered clearing agency, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity by, at a minimum, doing the following: [d]escribing the covered clearing agency's process to replenish any liquid resources that the clearing agency may employ during a stress event;''

[17] 17 CFR 240.17Ad–22(e)(2).

transparent'' and ''specify clear and direct lines of responsibility.'' The proposed amendments would ensure that it is clear that material breaches and unapproved deviations from the Treasury Documents would need to be reported to certain senior leaders and that those individuals would determine whether issues should be further escalated. The amendments therefore enhance the governance arrangements relating to breaches of the Treasury Documents.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments would apply uniformly to all CMs, are being adopted to strengthen and clarify the Clearing House's liquidity risk management processes and should not affect the rights or obligations of CMs. Further, the amendments are generally intended to simplify and streamline documentation and reflect current practices, rather than substantially alter existing practices. As a result, ICE Clear Europe does not believe the amendments would affect the cost of clearing for CMs or other market participants, the market for cleared services generally or access to clearing by CMs or other market participants, or otherwise affect competition among CMs or market participants in a manner not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change, Security-Based Swap Submission and Advance Notice and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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–ICEEU–2019–012 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–ICEEU–2019–012. 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, security-based swap submission or advance notice that are filed with the Commission, and all written communications relating to the proposed rule change, security-based swap submission or advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.* All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2019–012 and should be submitted on or before August 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15777 Filed 7–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86418; File No. SR–ICEEU–2019–016]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change, Security-Based Swap Submission or Advance Notice Relating to Amendments to the ICE Clear Europe Delivery Procedures

July 19, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 11, 2019, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(4)(ii) thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change, Security-Based Swap Submission, or Advance Notice

The principal purpose of the proposed amendments is for ICE Clear Europe to amend its Delivery Procedures (the ''Delivery Procedures'') to add delivery terms relating to the ICE

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3).

[4] 17 CFR 240.19b–4(f)(4)(ii).

Futures Europe New York Harbour Ultra Low Sulphur Diesel Futures Contracts (the ''ICE NYH ULSD Futures Contracts'') and the ICE Futures Europe New York Harbour Ultra Low Sulphur Heating Oil Futures Contracts (the ''NYH ULSHO Futures Contracts'', and collectively, the ''Contracts'').[5]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission or Advance Notice

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change, Security-Based Swap Submission or Advance Notice

(a) Purpose

ICE Clear Europe is proposing to amend its Delivery Procedures to add a new Section 11 and Part FF regarding delivery procedures relating to the Contracts, which will be traded on ICE Futures Europe and cleared by ICE Clear Europe.

Proposed Part FF would set out the delivery specifications and procedures for deliveries of fungible 15 ppm ultra low sulphur diesel fuel in respect of the ICE NYH ULSD Futures Contract, and fungible 15 ppm ultra low sulphur heating oil in respect of the ICE NYH ULSHO Futures Contract. The amended Delivery Procedures would specify the Buyer's delivery options (delivery into Buyer's barge, into Buyer's tanker, by inter-tank transfer (where certain conditions are satisfied) or by in-tank transfer at the relevant terminal (subject to the terms of business of the terminal)). Consistent with the exchange rules for the Contracts, delivery will take place on a business day nominated by the Buyer (pursuant to a specified delivery nomination form), subject to approval or rejection by the Seller, within a five-day delivery range agreed by the Seller and Buyer. Proposed Part FF would also establish certain timing requirements for exchange of futures for physical and swap transactions under exchange rules.

Proposed Part FF would provide a detailed delivery timetable, from the last trading day of the Contracts through final settlement, including procedures, deadlines and requirements for nominations of delivery range and delivery day, delivery confirmations, invoicing, provision of Buyer's and Seller's security, release of security following completion of delivery and other matters. The procedures would address invoice calculation with respect to the Contracts and delivery tolerances. Proposed Part FF would also specify the delivery documentation required of Buyers and Sellers.

Proposed new Section 11 of the Delivery Procedures would further specify the alternative delivery procedure for the Contracts if the Buyer and Seller agree to undertake delivery outside the ICE Futures Europe Rules.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act[6] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments are designed to facilitate the clearing of a new physically settled ultra low sulphur diesel futures contract and a new ultra low sulphur heating oil futures contract that are being launched for trading by the ICE Futures Europe exchange and that will be cleared by ICE Clear Europe. The amendments would set out the obligations and roles of the Clearing House and the relevant parties for delivery under the Contracts, supplementing the existing provisions of the Rules. ICE Clear Europe believes that its financial resources, risk management, systems and operational arrangements are sufficient to support clearing of such Contracts (and to address physical delivery under such Contracts) and to manage the risks associated with such Contracts. As a result, in ICE Clear Europe's view, the amendments would be consistent with the prompt and accurate clearance and settlement of the Contracts as set out in the proposed Delivery Procedures amendments, and the protection of investors and the public interest consistent with the requirements of Section 17A(b)(3)(F) of the Act.[7] (In ICE Clear Europe's view, the amendments would not adversely affect the safeguarding of funds or securities in the custody or control of the clearing agency or for which it is responsible, within the meaning of Section 17A(b)(3)(F).[8])

In addition, Rule 17Ad–22(e)(10)[9] requires that each covered clearing agency establish and maintain transparent written standards that state its obligations with respect to the delivery of physical instruments, and establish and maintain operational practices that identify, monitor and manage the risks associated with such physical deliveries. As discussed above, the amendments to the Delivery Procedures relating to the delivery and settlement under the Contracts and ICE Futures Europe exchange rules would set out the obligations and roles of Clearing Members and the Clearing House. The amendments would also adopt relevant procedures for such deliveries, which would facilitate identifying, monitoring and managing risks associated with delivery.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The changes are being proposed in order to update the Delivery Procedures in connection with the listing of the Contracts for trading on the ICE Futures Europe market. ICE Clear Europe believes that the Contracts would provide additional opportunities for interested market participants to engage in trading activity in the New York Harbour ultra low sulphur diesel and ultra low sulphur heating oil market. ICE Clear Europe does not believe the amendments would adversely affect competition among Clearing Members, materially affect the cost of clearing, adversely affect access to clearing in Contracts for Clearing Members or their customers, or otherwise adversely affect competition in clearing services. Accordingly, ICE Clear Europe does not believe that the amendments would impose any impact or burden on competition that is not appropriate in furtherance of the purpose of the Act.

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 17 CFR 240.17Ad–22(e)(10).

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to the proposed amendments.

III. Date of Effectiveness of the Proposed Rule Change, Security-Based Swap Submission and Advance Notice and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and paragraph (f) of Rule 19b–4 [11] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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–ICEEU–2019–016 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–ICEEU–2019–016. 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, security-based swap submission or advance notice that are filed with the Commission, and all written communications relating to the proposed rule change, security-based swap submission or advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation*.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2019–016 and should be submitted on or before August 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15775 Filed 7–24–19; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86412; File No. SR–NASDAQ–2019–057]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Amend Rule 4121

July 19, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 16, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 4121 (Trading Halts Due to Extraordinary Market Volatility) to enhance the re-opening auction process for Nasdaq listed securities following trading halts due to extraordinary market volatility.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the re-opening auction process for Nasdaq listed securities following trading halts due to extraordinary market volatility (*i.e.,* ''market-wide circuit breakers'') to be similar to the process currently employed following a Trading Pause initiated pursuant to the Plan to Address Extraordinary Market Volatility (*i.e.,* the ''Limit Up-Limit Down'' or ''LULD'' Plan). In 2017, the Exchange amended its auction process for re-opening a Nasdaq listed security following a Trading Pause initiated pursuant to the LULD Plan.[3] Specifically, the Exchange modified its rules such that initial Auction Collars following a Trading Pause would be calculated using a new methodology based on the Price Band that triggered the Trading Pause, and instituted the process for extending the auction and

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 79876 (January 25, 2017), 82 FR 8888 (January 31, 2017) (SR–NASDAQ–2016–131).

further widening the collars if necessary to accommodate buy or sell pressure outside of the collars then in effect. The Exchange believes that these changes have been effective in facilitating a fair and orderly market following Trading Pauses initiated pursuant to the Limit Up-Limit Down Plan, and has decided to implement similar functionality for trading halts in Nasdaq listed securities following the initiation of market-wide circuit breakers.[4] The Exchange believes that the proposed changes would promote price formation and provide a more consistent re-opening process for members and investors following such trading halts, similar to the current implementation on NYSE Arca, Inc. (''Arca'') and Cboe BZX Exchange, Inc. (''BZX'').[5]

Today, trading in Nasdaq listed securities would resume on the Exchange in most cases through a Halt Cross,[6] including after a Level 1 or Level 2 market-wide circuit breaker trading halt initiated under Rule 4121. In particular, Rule 4121(c)(i) provides that the re-opening of trading following a Level 1 or Level 2 trading halt shall follow the procedures set forth in Rule 4120. These procedures are in Rule 4120(c)(7), which provides, in relevant part, for a 5-minute Display Only Period during which market participants may enter quotes and orders in Nasdaq systems, at the conclusion of which trading will immediately resume through the Halt Cross under Rule 4753.[7] Additionally, the Exchange will extend the Display Only Period for an additional 1-minute period if there is volatility during the Display Only Period (*i.e.,* an order imbalance in the security). The volatility checks are governed under Rule 4120(c)(7)(C)(1) and (2), and provides that the Display Only Period will be extended if: (i) The expected cross price moves the greater of 5% or 50 cents, or (ii) all market orders will not be executed in the cross. The Exchange now proposes to amend this process such that for the resumption of trading after a Level 1 or Level 2 market-wide circuit breaker trading halt, the Exchange proposes to instead follow a process similar to that currently applied for releasing a security following a Trading Pause initiated under the LULD Plan, which is described in Rule 4120(c)(10).

Rule 4120(c)(10), which describes the current process for resuming trading after a Trading Pause, provides for an initial auction period and additional auction periods with widening price collars should the security fail to conclude each auction period. For any such security listed on Nasdaq, prior to terminating the pause, there is a 5-minute initial Display Only Period during which market participants may enter quotations and orders in that security in Nasdaq systems. During this initial period, the Exchange also establishes the auction reference price (hereinafter ''LULD Auction Reference Price''),[8] as well as the upper and lower auction collar (hereinafter, ''LULD Auction Collar'') prices.[9] The security is released at the end of the initial Display Only Period unless the Exchange detects an order imbalance [10] in the security, in which case the initial Display Only Period is extended for an additional five minutes, and the LULD Auction Collar prices are further widened by 5% increments (or $0.15 for securities with a LULD Auction Reference Price of $3 or less) in the direction of the order imbalance.[11] At the end of the first extended Display Only Period, the security is released for trading unless there is an order imbalance in the security, in which case the extended Display Only Period will be further extended every five minutes in the manner described in Rule 4120(c)(10)(B) until the security is released for trading. The security is released for trading at the first point there is no order imbalance.

Proposal

The Exchange now proposes to implement this process for resuming trading following a market-wide circuit breaker under Rule 4121 as well. As noted above, the current re-opening process for a Level 1 or Level 2 trading halt initiated under Rule 4121 does not have a mechanism for calculating price collars and a process for widening the collars if necessary to accommodate buy or sell pressure outside of the collars then in effect. The Exchange therefore believes that its proposal will facilitate a fair and orderly market following such trading halts initiated pursuant to a Level 1 or Level 2 market-wide circuit breaker that is designed to reduce the potential for significant price disparity in post-auction trading. The proposed process for re-opening a Nasdaq listed security under Rule 4121 would be substantially similar to the re-opening process employed today for Trading Pauses under Rule 4120(c)(10), with certain differences discussed below, primarily related to the calculation of the halt auction collars.

Accordingly, the Exchange will provide in new paragraph (d) to Rule 4121 that a Level 1 or Level 2 trading halt initiated under this Rule (''MWCB Halt'') shall be terminated when Nasdaq releases the security for trading.[12] For any such security listed on Nasdaq, prior to terminating the MWCB Halt, there will be a 15-minute ''Initial Display Only Period'' during which market participants may enter quotations and orders in that security in Nasdaq systems. The Initial Display Only Period will be 15 minutes in duration instead of the 5 minute initial display only period currently employed for Trading Pauses under Rule 4120(c)(10) to coincide with the entire duration of a MWCB Halt.[13] The Exchange believes that the proposed Initial Display Only Period would provide additional time to attract offsetting interest, and would help address order imbalances that may not be resolved within the current 5-minute period.

Proposed Rule 4121(d)(1)(A) will provide that during the Initial Display Only Period, the Exchange will also establish the ''Auction Reference Price.'' The Auction Reference Price shall mean the Nasdaq last sale price (either round

[4] A market-wide circuit breaker is triggered if the price of the S&P 500 Index declines by a specified amount compared to the closing price for the immediately preceding trading day. *See* Rule 4121.

[5] Both Arca and BZX implemented similar processes for resuming trading following non-LULD regulatory halts (which include trading halts following market-wide circuit breakers). *See* Securities Exchange Act Release Nos. 79846 (January 19, 2017), 82 FR 8548 (January 26, 2017) (SR–NYSEArca–2016–130); and 84927 (December 21, 2018), 83 FR 67768 (December 31, 2018) (SR–CboeBZX–2018–090).

[6] The Halt Cross process is set forth in Rule 4753. As discussed in more detail later in this filing, the Halt Cross does not apply to the re-opening of a Nasdaq listed security following a Trading Pause initiated under the LULD Plan, which instead re-opens pursuant to Rule 4120(c)(10).

[7] The Exchange would then re-open the Nasdaq listed security that was subject to the Level 1 or Level 2 market-wide circuit breaker trading halt at an execution price determined pursuant to the execution algorithm in Rule 4753(b)(2)(A)–(D), which sets forth a series of tie-breakers for selecting the execution price of the Halt Cross.

[8] *See* Rule 4120(c)(10)(A)(i).

[9] *See* Rule 4120(c)(10)(A)(ii). In contrast, price collars would not be established for re-opening a Nasdaq listed security after a Level 1 or Level 2 market-wide circuit breaker trading halt today. As noted above, the Exchange would instead re-open at an execution price determined pursuant to the execution algorithm in Rule 4753(b)(2)(A)–(D). See *supra* note 8.

[10] For purposes of Rule 4120(c)(10), an order imbalance is established if: (i) The calculated price at which the security would be released for trading is outside the applicable Auction Collar prices calculated under paragraphs (A), (B), or (C) of Rule 4120(c)(10); or (ii) all market orders would not be executed in the cross. *See* Rule 4120(c)(10)(E).

[11] *See* Rule 4120(c)(10)(B).

[12] Rule 4121(c)(i) currently points to Rule 4120 for the re-opening process following a MWCB Halt. The new re-opening process will be set forth in proposed Rule 4121(d), so the Exchange will delete this portion from the current Rule.

[13] *See* Rule 4121(b).

or odd lot) after 9:15 a.m. Eastern Time (''ET'') but prior to the MWCB Halt and, if none, the prior trading day's Nasdaq Office Closing Price (''NOCP''). The Exchange is not proposing to use the LULD Auction Reference Price, which is based on the Price Band that triggered the Trading Pause, as the Exchange believes that a different reference is necessary for a re-opening process that is unrelated to the LULD mechanism. The Exchange has chosen to use the last Nasdaq sale price prior to the MWCB Halt (or if none, the prior trading day's NOCP) in this circumstance as this price is reflective of the current market for the halted security. The Exchange's proposal is similar to the current implementation on Arca and BZX.[14]

Proposed Rule 4121(d)(1)(B) will describe how the Exchange would calculate the upper and lower ''MWCB Auction Collar'' prices during the Initial Display Period. Specifically, the initial upper and lower collar prices would be determined as follows:

- The lower MWCB Auction Collar is derived by subtracting from the Auction Reference Price 10% of the Auction Reference Price, rounded to the nearest minimum price increment,[15] or in the case of securities with an Auction Reference Price of $5 or less, $0.50.
- The upper MWCB Auction Collar is derived by adding to the Auction Reference Price 10% of the Auction Reference Price, rounded to the nearest minimum price increment, or in the case of securities with an Auction Reference Price of $5 or less, $0.50.

In contrast, the initial price collar thresholds currently used for the LULD mechanism are applied only in the direction of the trading that invoked the Trading Pause.[16] In this case, because there would not be a security-specific pricing direction reason for the MWCB Halt, the Exchange believes that it is appropriate to apply the initial thresholds on both sides of the Auction Reference Price. For example, if the Nasdaq last sale price (either round or odd lot) after 9:15 a.m. ET but prior to the MWCB Halt for a security is $100.00, then the lower and upper initial MWCB Auction Collar prices would be $90 and $110—*i.e.,* 10% below and above the Nasdaq last sale price. This mirrors the application of the initial halt auction collars on both Arca and BZX today, except the Exchange's proposed MWCB Auction Collar threshold amounts will be 10% of the Auction Reference Price (or $0.50 for securities priced $5 or less).[17] The Exchange believes that the wider parameters proposed for MWCB Auction Collars are set at appropriate levels that would allow the Exchange to re-open trading in securities more quickly while still reducing the potential to re-open at a price that is significantly away from the last traded price of the security. Furthermore, the Exchange has traditionally been a listing venue for equity stocks, while Arca and BZX have traditionally listed more ETFs. ETFs track entire sectors, indices or other groups of assets, which can mute the effect of price volatility of the ETF. The Exchange therefore believes that the wider price bands proposed herein strikes an appropriate balance between allowing the Exchange to return to normal continuous trading in a measured, timely manner while accommodating the potential higher volatility of individual stocks.

Proposed Rules 4121(d)(2) and (d)(3) will specify the circumstances when the Exchange would extend the Display Only Period for a MWCB Halt re-opening process, and how the Exchange would adjust the MWCB Auction Collars for each extension. In particular, at the conclusion of the Initial Display Only Period, the security will be released for trading unless, at the end of the Initial Display Only Period, Nasdaq detects an order imbalance in the security.[18] In that case, Nasdaq will extend the Display Only Period for an additional 5-minute period (''Extended Display Only Period''), and the MWCB Auction Collar prices will be adjusted as follows:

- If the Display Only Period is extended because the calculated price at which the security would be released for trading is below the lower MWCB Auction Collar price or all sell market orders would not be executed in the cross, then the new lower MWCB Auction Collar price is derived by subtracting 10% of the Auction Reference Price, which was rounded to the nearest minimum price increment, or in the case of securities with an Auction Reference Price of $5 or less, $0.50, from the previous lower MWCB Auction Collar price, and the upper MWCB Auction Collar price will not be changed.
- If the Display Only Period is extended because the calculated price at which the security would be released for trading is above the upper MWCB Auction Collar price or all buy market orders would not be executed in the cross, then the new upper MWCB Auction Collar price is derived by adding 10% of the Auction Reference Price, which was rounded to the nearest minimum price increment, or in the case of securities with an Auction Reference Price of $5 or less, $0.50, to the previous upper MWCB Auction Collar price, and the lower MWCB Auction Collar price will not be changed.

At the conclusion of the Extended Display Only Period, the security will be released for trading unless, at the end of the Extended Display Only Period, Nasdaq detects an order imbalance in the security. In that case, Nasdaq will further extend the Display Only Period, continuing to adjust the MWCB Auction Collar prices every five minutes in the manner described in Rule 4121(d)(2) until the security is released for trading; provided, however, that Nasdaq will not adjust the MWCB Auction Collar prices past 50% of the Auction Reference Price for any security during any Extended Display Only Period. During any additional Extended Display Only Period after the first Extended Display Only Period, Nasdaq shall release the security for trading at the first point there is no order imbalance.

As proposed, the process for initiating extensions of the Display Only Period for a MWCB Halt auction will be identical to the process currently used for extending Trading Pauses, with only two differences that relate to the calculation of the auction collars. First, for each extension period, the MWCB Auction Collars would be widened in the direction of the imbalance using the wider parameters described above for the initial MWCB Auction Collar (*i.e.,*

[14] *See* Arca Rule 7.35–E(a)(8)(A) and BZX Rule 11.23(a)(9). *See also* SR–CboeBZX–2018–090 for discussion of similarities between Arca's and BZX's auction reference prices for non-LULD regulatory halts. The Exchange's proposed Auction Reference Price for MWCB Halts is substantially similar to Arca's and BZX's auction reference prices, except the Exchange will use the last Nasdaq sale price prior to the MWCB Halt, as described above. The Exchange believes that it is appropriate to use the price of a trade on the primary listing market, *i.e.,* Nasdaq, to set the reference price for auctions in Nasdaq listed securities when such a trade has been executed recently.

[15] The term ''minimum price increment'' means $0.01 in the case of a System Security priced at $1 or more per share, and $0.0001 in the case of a System Security priced at less than $1 per share. *See* Rule 4107(k). Thus, for example, if adding 10% of the Auction Reference Price to the MWCB Auction Collar would result in a tenth of a penny, the Exchange would round down to the nearest penny when the calculation results in one to four tenths of a penny, and the Exchange would round up to the nearest penny when the calculation results in five to nine tenths of a penny.

[16] *See* Rule 4120(c)(10)(A)(ii).

[17] Both Arca and BZX employ auction collar thresholds identical to the parameters currently used for LULD auction collars (*i.e.,* 5% of the auction reference price, or $0.15 for securities with an auction reference price of $3 or less). *See* Arca Rule 7.35–E(e)(7)(B)(ii) and BZX Rule 11.23(d)(2)(C)(i)(B).

[18] As discussed below, an order imbalance under the proposed re-opening process for MWCB Halts will be established in the same manner as an order imbalance under the current LULD re-opening process as set forth in Rule 4120(c)(10)(E).

by an additional 10% or $0.50 for securities with an Auction Reference Price of $5 or less) as opposed to the parameters currently used to widen LULD Auction Collars (*i.e.,* by an additional 5% or $0.15 for securities with a reference price of $3 or less). Second, the Exchange would not adjust the MWCB Auction Collars past 50% of the Auction Reference Price for any security during any Extended Display Only Period, whereas under the current LULD mechanism, the price collars would continue to be adjusted for each extension period.[19] For example, a security with an Auction Reference Price of $3 would have initial lower and upper MWCB Auction Collar prices of $2.50 and $3.50. If all buy market orders would not be executed in the cross at the end of the Initial Display Only Period, the Exchange would extend the Display Only Period and widen the upper MWCB Auction Collar price to $4.00. The lower MWCB Auction Collar price would remain at $2.50. If there continues to be any buy side imbalance at the end of the first Extended Display Only Period, the Exchange would further adjust the upper collar price to $4.50 (while keeping the lower collar at $2.50) for the second extension period. To the extent there are subsequent Extended Display Only Periods to accommodate buy side trading interest, the Exchange would not adjust the upper MWCB Auction Collar past $4.50 (*i.e.,* 50% of the Auction Reference Price), and would continue to use this price threshold for the duration of the MWCB Halt, until the security is released for trading.

As mentioned above, unlike the current implementation of auction collars under LULD as well as similar MWCB auction collars on Arca and BZX, the Exchange will not adjust the MWCB Auction Collars past 50% of the Auction Reference Price. The Exchange recognizes that the proposed 50% limit for adjusting the MWCB Auction Collars may prevent the transition to continuous trading, particularly in instances of extreme price volatility that could result in increased Extended Display Only Periods. On the other hand, however, if there was no limit on adjusting the price collars, there is potential for extreme volatility resulting in trades at prices far away from a security's fundamental value, ultimately harming investors that are party to the trade. The Exchange considered using the same logic as currently implemented under the LULD mechanism (*i.e.,* where there is no limit on adjusting the price collars) and ultimately determined not to align its proposal in this manner. The Exchange believes that it may be more appropriate to continue adjusting price collars in the context of LULD where trading is halted due to a period of extraordinary volatility in a single security (as opposed to all securities under a MWCB Halt) because there may be instances of a discrete event (such as the announcement of material news) that ultimately impacts the value of the individual security. A MWCB Halt, however, will be triggered during a period of significant volatility across markets that may not correlate to the fundamental value of a single security. As such, the Exchange believes that by proposing to adjust the MWCB Auction Collars up to 50% of the Auction Reference Price, an appropriate balance can be achieved in favor of preventing extraordinary volatility that could result in significant price disparity in post-auction trading.

Proposed Rule 4121(d)(4) will specify that an order imbalance would be established for purposes of the process under Rule 4121 as follows: [20]

- The calculated price at which the security would be released for trading is above (below) the upper (lower) MWCB Auction Collar price calculated under paragraphs (1), (2), or (3) of Rule 4121(d); or
- all market orders would not be executed in the cross.

Proposed Rule 4121(d)(5) will describe how the MWCB Auction Collars will function in the event of more than one trading halt initiated under Rule 4121 in the same day. In the event of a Level 2 Market Decline while a security is in a Level 1 MWCB Halt and has not been released for trading, Nasdaq will recalculate the lower and upper MWCB Auction Collar prices in the particular security in accordance with paragraph (1)(B) of Rule 4121.[21] In this instance, the Exchange will start the calculation of the new upper and lower MWCB Auction Collar prices using 10% of the Auction Reference Price, rounded to the nearest minimum price increment, or $0.50 for securities with an Auction Reference Price of $5 or less. The Exchange believes that the proposed language would bring greater transparency to market participants in how the Exchange would handle the calculation of MWCB Auction Collars.

The Exchange also proposes to add new paragraph (e) to Rule 4121 to describe how the Exchange will handle the publication of MWCB Halt Information. Specifically, at the beginning of the Initial Display Only Period and continuing through the resumption of trading, Nasdaq will disseminate by electronic means an Order Imbalance Indicator [22] every second. The Exchange also proposes to make a related change by adding new Rule 4753(a)(3)(G), which will provide that for purposes of a MWCB Halt initiated pursuant to Rule 4121, the Order Imbalance Indicator will include Auction Reference Prices and MWCB Auction Collars, as defined in Rule 4121(d).

The Exchange also proposes a number of formatting clean-ups in Rule 4121. In light of the above changes, Rule 4121(d) will be renumbered as Rule 4121(f). Finally, subparagraphs (i)–(iv) in Rule 4121(a) and subparagraphs (i)–(ii) in Rule 4121(b) will be renumbered as subparagraphs (1)–(4) and subparagraphs (1)–(2), respectively, for greater consistency with the Rulebook.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[23] in general, and furthers the objectives of Section 6(b)(5) of the Act,[24] 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.

The Exchange believes that the proposed rule change is consistent with the Act because it would amend the halt auction process following a MWCB Halt to be more closely aligned with the process currently implemented for halt auctions following a Trading Pause under the LULD Plan. The Exchange amended its re-opening process following a Trading Pause to better

[19] Thus as proposed, if the upper or lower MWCB Auction Collar is already adjusted by 50% of the Auction Reference Price for any extension period, that price threshold will be used for the duration of the MWCB Halt, until the security is released for trading.

[20] This is the same manner in which an order imbalance is established under the current re-opening process for Trading Pauses. *See* Rule 4120(c)(10)(E).

[21] As currently provided in Rule 4121(b)(i), the Exchange would halt trading based on a Level 1 or Level 2 Market Decline only once per day. Thus for example, if a Level 1 Market Decline were to occur and trading were halted, following the re-opening of trading, the Exchange would not halt the market again unless a Level 2 Market Decline were to occur.

[22] As described in Rule 4753(a)(3), an ''Order Imbalance Indicator'' is a message disseminated by electronic means containing information about Eligible Interest and the price at which such interest would execute at the time of dissemination.

''Eligible Interest'' is defined as any quotation or any order that has been entered into the system and designated with a time-in-force that would allow the order to be in force at the time of the Halt Cross. *See* Rule 4753(a)(5).

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

account for buy or sell pressure by changing the manner in which initial LULD Auction Collars are established, and widening the collars as appropriate to accommodate trading interest submitted to participate in the auction. The Exchange believes that these changes have been generally successful in facilitating a fair and orderly process for re-opening securities following a Trading Pause. The Exchange has therefore decided to use a similar process for halt auctions following a MWCB Halt. The Exchange believes that its proposal would benefit investors by facilitating price discovery and promoting more consistency in how the Exchange conducts the re-opening process following a Trading Pause or a MWCB Halt.

While the proposed re-opening process following MWCB Halts would largely follow the re-opening process in place today for Trading Pauses, there would be several notable differences. These differences are primarily designed to ensure that suitable MWCB Auction Collars are utilized for the re-opening process following MWCB Halts. For instance, while an Auction Reference Price based on the Price Band that triggered the Trading Pause continues to be appropriate in the context of the re-opening process following Trading Pauses, the Exchange believes that a different reference is necessary for the re-opening process for MWCB Halts. The Exchange has chosen to use the Nasdaq last sale price and, if none, the prior trading day's NOCP as the MWCB Auction Reference Price in these circumstances as this price is reflective of the current market for the halted security. Similarly, the Exchange believes that it is appropriate to calculate both upper and lower MWCB Auction Collars that are a specified percentage or dollar amount from this reference price because MWCB Halts do not involve security specific buy or sell pressure. These differences are similar to the application of MWCB Auction Collars on Arca and BZX today, except for the parameters used to calculate the price collars.[25] The Exchange believes that the wider parameters of 10% increments (or $0.50 for securities priced at $5 or less) proposed above for MWCB Auction Collars when compared to the parameters of 5% increments (or $0.15 for securities priced at $3 or less) currently used to calculate the LULD Auction Collars are set at appropriate levels that would allow the Exchange to re-open trading in securities more quickly while still reducing the potential for re-opening at a price that is significantly away from the last traded price of the security. Furthermore, the Exchange believes that it is appropriate to stop widening the MWCB Auction Collar prices past 50% of the Auction Reference Price to ensure that upon the resumption of trading after an MWCB Halt, the security is priced at a reasonable level from the Auction Reference Price.[26]

Otherwise, the proposed re-opening process for MWCB Halts is consistent with the current LULD re-opening process. Similar to the current LULD re-opening process, the Exchange also believes that the proposed process is consistent with the protection of investors and the public interest because they are designed to facilitate price discovery by ensuring that all market order interest could be satisfied in the auction process following MWCB Halts. Furthermore, the Exchange believes that the standardized procedures to extend MWCB Halt auctions an additional five minutes are appropriate because this would provide additional time to attract offsetting liquidity. If at the end of such extension, market orders still cannot be cannot be satisfied within the applicable collars, or if the re-opening price would be outside of the applicable collars, the Exchange would extend the halt auction process an additional five minutes. The Exchange believes that extending the auction in these circumstances would protect investors and the public interest by reducing the potential for significant price disparity in post-auction trading. With each such extension, the Exchange believes that it is appropriate to widen the price collar threshold on the side of the market on which there is buying or selling pressure as market conditions may prevent an order imbalance from being resolved within the prior auction collars.

The Exchange also believes it is appropriate to add language clarifying how the MWCB Auction Collars will function in the event of more than one trading halt initiated under Rule 4121 in the same day. The proposed changes would increase transparency in how the Exchange would handle the calculation of MWCB Auction Collars, and is therefore consistent with the public interest and the protection of investors. The Exchange likewise believes that specifying how it will handle the publication of MWCB Halt information will bring greater transparency around the operation of the Exchange's auction process.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to provide for a measured and transparent process for re-opening Nasdaq listed securities after a MWCB Halt that is similar to the current re-opening process following a Trading Pause initiated under the LULD Plan and the process already implemented on Arca and BZX for non-LULD regulatory halts.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–057 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.

[25] *See supra* notes 14 and 17 above, with accompanying text.

[26] As noted above, this is different from the current implementation of the price collars under the LULD mechanism where the price collars continue to be adjusted for each extension period. This also differs from the current implementation of non-LULD price collars on Arca and BZX, which both mirror the LULD process in this respect.

All submissions should refer to File Number SR–NASDAQ–2019–057. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–NASDAQ–2019–057 and should be submitted on or before August 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15776 Filed 7–24–19; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86415; File No. SR—CboeEDGX–2019–046]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Update Rule 16.1 To Include the Definition of Capacity, as well as Amend Its Fee Schedule To Reflect This Update

July 19, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 17, 2019, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Options'') proposes to update Rule 16.1 to include the definition of capacity, as well as amend its fee schedule to reflect this update. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add ''capacity'' as a defined term under Rule 16.1 (Definitions). The proposed change intends to codify the definition of capacity in it rules, which is currently referenced in its technical specifications[5] and in certain rules.[6] This proposed change is also a harmonizing change intended to conform to the capacity definition under the rules of its affiliated exchange, Cboe C2 Exchange, Inc. (''C2''). The Exchange also proposes to update a term under Rule 20.7 (Audit Trail) to reflect the proposed capacity definition. In addition to this, the Exchange proposes to conform certain definitions under its fee schedule to this proposed definition.

Currently, the System[7] allows for a User to mark its order with various capacity codes which correspond to the capacity of the User (*i.e.,* a customer, a Market Maker, etc.),[8] and, pursuant to current Exchange Rules, Users are required to submit orders with the proper capacity identification.[9] The current Exchange Rules, however, do not provide for a specific definition of the capacity in which a User may submit an order nor for the corresponding codes for different User capacity types. Additionally, the current fee schedule provides that a Member's transaction is assigned a fee code and defines the various types (*i.e.,* capacity type) of Members to which the corresponding fee codes are assigned. Specifically, the Member type definitions apply to any transaction identified by such Member. For example, ''Market Maker'' applies to any transaction identified by a Member for clearing in the Market Maker range at the OCC, where such Member is registered with the Exchange as a Market Maker.

The Exchange now proposes to amend Rule 16.1 to codify the definition of ''capacity''. The Exchange proposes to define ''capacity'' to mean the capacity in which a User submits an order, which the User specifies by applying the corresponding code to the order. The proposed corresponding codes and capacity types include: ''B'' to an order for the account of a broker dealer, including a foreign broker dealer; ''C'' to an order for the account of a Priority Customer; ''F'' to an order for the proprietary account of an OCC clearing member firm; ''J'' to an order for a joint back office account; ''M'' to an order for the account of a registered Market

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* Cboe Options Exchanges Binary Order Entry Specification, available at *http://cdn.batstrading.com/resources/membership/US_Options_BOE_Specification.pdf.*

[6] *See* Rule 18.2, Rule 20.7(b), and Rule 21.10.

[7] The automated trading system used by EDGX Options for the trading of options contracts. *See* Rule 16.1.

[8] *See* Cboe Options Exchanges Binary Order Entry Specification, available at *http://cdn.batstrading.com/resources/membership/US_Options_BOE_Specification.pdf.*

[9] *See* Rule 20.7.

Maker; ''N'' to an order for the account of a market maker, *i.e.,* an Away Market Maker; and ''U'' to an order for the account of a Professional.[10]

This definition is substantially similar to that of the definition under C2 Rule 1.1. The Exchange notes only slight differences between its proposed rule and that of its affiliated exchange, C2. First, the Exchange provides that capacity code ''C'' applies to orders for the account of a Priority Customer, whereas capacity code ''C'' under C2 Rule 1.1 applies to orders for the account of Public Customer. This difference accounts for the fact that C2 does not have a defined term for Priority Customer, which pursuant to Rule 16.1, means any person or entity that is not a broker or dealer in securities or a Professional. The Exchange believes that incorporating this term, as opposed to Public Customer, maintains consistency with the Exchange's fee schedule, which already excludes brokers or dealers and Professionals from the definition of the term Customer for purposes of pricing on the Exchange, and provides that Professional capacity types are to be separately marked as such. Second, the Exchange provides that capacity code ''N'' is assigned to an order for the account of a market maker on another options exchange, and is otherwise known as an Away Market Maker. C2 does not provide in its definition that this capacity type is otherwise known as an Away Market Maker. The Exchange's fee schedule currently defines Away Market Maker to mean the same as this proposed rule definition. Therefore, the Exchange believes that incorporating this language is a non-substantive addition that does not alter the capacity type definition attached to capacity code ''N'' in any way, but rather maintains consistency with the Exchange's fee schedule. The Exchange also notes that it does not add capacity code ''L'' like that of C2 for non-trading permit holder affiliates as this capacity code is only applicable to participants on C2.[11]

The Exchange also proposes to update Rule 20.7 (Audit Trail) to reflect the proposed capacity definition under Rule 16.1(a). Specifically, current Rule 20.7(b) provides that order records relating to EDGX Options must contain certain information, including Member capacity pursuant to subparagraph (b)(6). The Exchange now proposes to update subparagraph (b)(6) to User capacity, which is in line with the proposed capacity definition under proposed Rule 16.1.

The Exchange also proposes to update the capacity type definitions of ''Away Market Maker'', ''Customer'', ''Firm'', ''Joint Back Office'', Market Maker'' and ''Professional'' in its fee schedule to reflect the proposed capacity definition and types under proposed Rule 16.1. Specifically, the Exchange notes the proposed change to the current language providing that the capacity types apply to transactions identified by a Member for clearing in the respective capacity type range at the OCC. The Exchange updates this language to provide that the defined capacity types apply to orders for the account of the respective capacity type.[12] This change reflects the proposed capacity type definitions under proposed Rule 16.1 and is in line with the capacity codes applicable to participants on the Exchange's affiliated exchange, C2. The Exchange also believes that changing the definition of the capacity types to apply to an order for the account of the respective capacity types better aligns with the order identification requirements under Rule 20.7. Under Rule 20.7 a Member must submit proper order information when entering orders and maintain Customer order records that must contain, among other things, User capacity (as proposed). The Exchange believes that codifying in the Rules the codes that Users must apply to orders for the accounts of the various capacity types will provide additional transparency to Members regarding the appropriate order marking requirements.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[13] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed change to adopt the definition of capacity, including types and codes, will remove impediments to and perfect the mechanism of a free and open market and a national market system by providing Users with rules that accurately reflect and add detail to current System capacity code specifications for which a User must use to appropriately mark its orders. As a result, the proposed change will help facilitate understanding of and compliance with the rules. In addition to this, the Exchange believes that by harmonizing the definition of capacity types and codes, with that of its affiliated exchange, C2, will result in increased understanding of the Exchange's Rules and that of its affiliated exchange rules for those participating across the two affiliated exchanges.

Additionally, the Exchange believes that the proposed change to reflect the proposed capacity definition throughout the corresponding definitions in the fee schedule will provide Members with clearer definitions of capacity types that will better align with the Exchange Rules as well as provide detail to the System specifications already in place. As a result, the proposed change will mitigate any confusion surrounding the fee schedule capacity definitions and applicable codes. As such, increased User understanding of the Exchange's fee schedule definitions as they correspond to the Exchange Rules will serve to remove impediments to and perfect the mechanism of a free and open market, and thereby protect investors. Likewise, the Exchange believes that the proposed change to Rule 20.7(b)(6) to more accurately reflect the proposed definition of capacity will also serve to remove impediments to and perfect the mechanism of a free and open market by aligning the Exchange Rules, in turn bolstering Member understanding, and thus, facilitating less burdensome

[10] *See* Rule 16.1(a)(47) (proposed Rule 16.1). A Professional means any person or entity that is not a broker or dealer in securities and places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members.

[11] *See* supra note 5.

[12] Though the Exchange proposes to remove the OCC clearing range language in order to better align these fee schedule definitions with those under proposed 16.1 and C2 Rule 1.1, this does not alter the manner in which each capacity type clears at the OCC.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *Id.*

regulatory compliance with the audit trail rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change is not designed to address any competitive issues but is only intended to provide clarity with respect to the definition of capacity types and consistency throughout its Rules and fee schedule with respect to capacity codes. The Exchange does not believe that the proposed change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because all Users are already required to submit orders with the appropriate capacity code, and the same capacity codes are available to all Members. The Exchange also believes that the proposed rule change reduces the regulatory compliance burden on all Members by better aligning the Rules and fee schedule with the existing audit trail requirements. Moreover, the Exchange does not believe that the proposed change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted, the proposed rule change is not intended as a competitive change, but rather to provide Members with added detail and clarity regarding the capacity codes applicable to their orders submitted to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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 if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGX–2019–046 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGX–2019–046. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2019–046 and should be submitted on or before August 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15772 Filed 7–24–19; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 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 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.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86419; File No. SR–CboeBZX–2019–066]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Update Rule 16.1 To Include the Definition of Capacity, as Well as Amend Its Fee Schedule To Reflect This Update

July 19, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 17, 2019, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX Options'') proposes to update Rule 16.1 to include the definition of capacity, as well as amend its fee schedule to reflect this update. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add ''capacity'' as a defined term under Rule 16.1 (Definitions). The proposed change intends to codify the definition of capacity in it rules, which is currently referenced in its technical specifications [5] and in certain rules.[6] This proposed change is also a harmonizing change intended to conform to the capacity definition under the rules of its affiliated exchange, Cboe C2 Exchange, Inc. (''C2''). The Exchange also proposes to update a term under Rule 20.7(Audit Trail) to reflect the proposed capacity definition. In addition to this, the Exchange proposes to conform certain definitions under its fee schedule to this proposed definition.

Currently, the System [7] allows for a User to mark its order with various capacity codes which correspond to the capacity of the User (*i.e.,* a customer, a Market Maker, etc.),[8] and, pursuant to current Exchange Rules, Users are required to submit orders with the proper capacity identification.[9] The current Exchange Rules, however, do not provide for a specific definition of the capacity in which a User may submit an order nor for the corresponding codes for different User capacity types. Additionally, the current fee schedule provides that a Member's transaction is assigned a fee code and defines the various types (*i.e.,* capacity type) of Members to which the corresponding fee codes are assigned. Specifically, the Member type definitions apply to any transaction identified by such Member. For example, ''Market Maker'' applies to any transaction identified by a Member for clearing in the Market Maker range at the OCC, where such Member is registered with the Exchange as a Market Maker.

The Exchange now proposes to amend Rule 16.1 to codify the definition of ''capacity''. The Exchange proposes to define ''capacity'' to mean the capacity in which a User submits an order, which the User specifies by applying the corresponding code to the order. The proposed corresponding codes and capacity types include: ''B'' to an order for the account of a broker dealer, including a foreign broker dealer; ''C'' to an order for the account of a Priority Customer; ''F'' to an order for the proprietary account of an OCC clearing member firm; ''J'' to an order for a joint back office account; ''M'' to an order for the account of a registered Market Maker; ''N'' to an order for the account of a market maker, *i.e.,* an Away Market Maker; and ''U'' to an order for the account of a Professional.[10]

This definition is substantially similar to that of the definition under C2 Rule 1.1. The Exchange notes only slight differences between its proposed rule and that of its affiliated exchange, C2. First, the Exchange provides that capacity code ''C'' applies to orders for the account of a Priority Customer, whereas capacity code ''C'' under C2 Rule 1.1 applies to orders for the account of Public Customer. This difference accounts for the fact that C2 does not have a defined term for Priority Customer, which pursuant to Rule 16.1, means any person or entity that is not a broker or dealer in securities or a Professional. The Exchange believes that incorporating this term, as opposed to Public Customer, maintains consistency with the Exchange's fee schedule, which already excludes Professionals from the definition of the term Customer for purposes of pricing on the Exchange, and provides that Professional capacity types are to be separately marked as such. Second, the Exchange provides that capacity code ''N'' is assigned to an order for the account of a market maker on another options exchange, and is otherwise known as an Away Market Maker. C2 does not provide in its definition that this capacity type is otherwise known as an Away Market Maker. The Exchange's fee schedule currently defines Away Market Maker to mean the same as this proposed rule definition. Therefore, the Exchange believes that incorporating this language is a non-substantive addition that does not alter the capacity type definition attached to capacity code ''N'' in any way, but rather maintains consistency with the Exchange's fee schedule. The Exchange also notes that it does not add capacity code ''L'' like that of C2 for non-trading permit holder affiliates as this capacity code is only applicable to participants on C2.[11]

In addition to this, the proposed rule change alphabetizes the defined terms in Rule 16.1 and removes the paragraph lettering to conform to the format of C2 Rule 1.1 for its definitions.

The Exchange also proposes to update Rule 20.7 (Audit Trail) to reflect the proposed capacity definition under Rule 16.1(a). Specifically, current Rule 20.7(b) provides that order records relating to BZX Options must contain certain information, including Member capacity pursuant to subparagraph (b)(6). The Exchange now proposes to update subparagraph (b)(6) to User capacity, which is in line with the proposed capacity definition under proposed Rule 16.1.

The Exchange also proposes to update the capacity type definitions of ''Away Market Maker'', ''Customer'', ''Firm'', ''Joint Back Office'', Market Maker'' and ''Professional'' in its fee schedule to reflect the proposed capacity definition and types under proposed Rule 16.1.

[5] *See* Cboe Options Exchanges Binary Order Entry Specification, available at *http://cdn.batstrading.com/resources/membership/US_Options_BOE_Specification.pdf.*

[6] *See* Rule 18.2, Rule 20.7(b), and Rule 21.10.

[7] The automated trading system used by BZX Options for the trading of options contracts. *See* Rule 16.1.

[8] *See* Cboe Options Exchanges Binary Order Entry Specification, available at *http://cdn.batstrading.com/resources/membership/US_Options_BOE_Specification.pdf.*

[9] *See* Rule 20.7.

[10] *See* Rule 16.1(a)(47) (proposed Rule 16.1). A Professional means any person or entity that is not a broker or dealer in securities and places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members.

[11] *See* supra note 5.

Specifically, the Exchange notes the proposed change to the current language providing that the capacity types apply to transactions identified by a Member for clearing in the respective capacity type range at the OCC. The Exchange updates this language to provide that the defined capacity types apply to orders for the account of the respective capacity type.[12] This change reflects the proposed capacity type definitions under proposed Rule 16.1 and is in line with the capacity codes applicable to participants on the Exchange's affiliated exchange, C2. The Exchange also believes that changing the definition of the capacity types to apply to an order for the account of the respective capacity types better aligns with the order identification requirements under Rule 20.7. Under Rule 20.7 a Member must submit proper order information when entering orders and maintain Customer order records that must contain, among other things, User capacity (as proposed). The Exchange believes that codifying in the Rules the codes that Users must apply to orders for the accounts of the various capacity types will provide additional transparency to Members regarding the appropriate order marking requirements.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[13] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[14] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[15] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed change to adopt the definition of capacity, including types and codes, will remove impediments to and perfect the mechanism of a free and open market and a national market system by providing Users with rules that accurately reflect and add detail to current System capacity code specifications for which a User must use to appropriately mark its orders. As a result, the proposed change will help facilitate understanding of and compliance with the rules. In addition to this, the Exchange believes that by harmonizing the definition of capacity types and codes, as well as the format of all BZX Options definitions, with that of its affiliated exchange, C2, will result in increased understanding of the Exchange's Rules and that of its affiliated exchange rules for those participating across the two affiliated exchanges.

Additionally, the Exchange believes that the proposed change to reflect the proposed capacity definition throughout the corresponding definitions in the fee schedule will provide Members with clearer definitions of capacity types that will better align with the Exchange Rules as well as provide detail to the System specifications already in place. As a result, the proposed change will mitigate any confusion surrounding the fee schedule capacity definitions and applicable codes. As such, increased User understanding of the Exchange's fee schedule definitions as they correspond to the Exchange Rules will serve to remove impediments to and perfect the mechanism of a free and open market, and thereby protect investors. Likewise, the Exchange believes that the proposed change to Rule 20.7(b)(6) to more accurately reflect the proposed definition of capacity will also serve to remove impediments to and perfect the mechanism of a free and open market by aligning the Exchange Rules, in turn bolstering Member understanding, and thus, facilitating less burdensome regulatory compliance with the audit trail rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change is not designed to address any competitive issues but is only intended to provide clarity with respect to the definition of capacity types and consistency throughout its Rules and fee schedule with respect to capacity codes. The Exchange does not believe that the proposed change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because all Users are already required to submit orders with the appropriate capacity code, and the same capacity codes are available to all Members. The Exchange also believes that the proposed rule change reduces the regulatory compliance burden on all Members by better aligning the Rules and fee schedule with the existing audit trail requirements. Moreover, the Exchange does not believe that the proposed change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted, the proposed rule change is not intended as a competitive change, but rather to provide Members with added detail and clarity regarding the capacity codes applicable to their orders submitted to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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 if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the

[12] Though the Exchange proposes to remove the OCC clearing range language in order to better align these fee schedule definitions with those under proposed 16.1 and C2 Rule 1.1, this does not alter the manner in which each capacity type clears at the OCC.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] *Id.*

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 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 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.

Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2019–066 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2019–066. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change.

Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2019–066 and should be submitted on or before August 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15778 Filed 7–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86417; File No. SR–NYSEArca–2019–51]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Regarding Investments of the Janus Henderson Mortgage-Backed Securities ETF Currently Listed and Traded on the Exchange Under NYSE Arca Rule 8.600–E

July 19, 2019.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 9, 2019, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes certain changes regarding investments of the Janus Henderson Mortgage-Backed Securities ETF, shares of which are currently listed and traded on the Exchange under NYSE Arca Rule 8.600–E (''Managed Fund Shares''). The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes certain changes regarding investments of the Janus Henderson Mortgage-Backed Securities ETF (''Fund''), shares (''Shares'') of which are currently listed and traded on the Exchange under NYSE Arca Rule 8.600–E, which governs the listing and trading of Managed Fund Shares[4] on the Exchange. Shares of the Fund commenced listing and trading on the Exchange on September 12, 2018 under the generic listing standards under Commentary .01 to NYSE Arca Rule 8.600–E.

The Fund is a series of Janus Detroit Street Trust (''Trust'').[5] Janus Capital Management LLC is the Fund's investment adviser (''Adviser''). State Street Bank and Trust Company is the custodian and transfer agent (''Transfer Agent'') for the Fund. ALPS

[4] A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Investment Company Units, listed and traded on the Exchange under NYSE Arca Rule 5.2–E(j)(3), seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

[5] The Trust is registered under the 1940 Act. On February 28, 2019, the Trust filed with the Commission a registration statement on Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a) (''Securities Act'') and the 1940 Act relating to the Fund (File Nos. 333–207814 and 811–23112) (the ''Registration Statement''). The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 31540 (March 30, 2015) (''Exemptive Order'').

Distributors, Inc. is the distributor (''Distributor'') for the Fund's Shares.

Commentary .06 to Rule 8.600–E provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[6] In addition, Commentary .06 further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the open-end fund's portfolio. The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to such broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio. In the event (a) the Adviser becomes registered as a broker-dealer or newly affiliated with one or more broker-dealers, 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 its broker-dealer affiliate regarding access to information concerning the composition 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.

Janus Henderson Mortgage-Backed Securities ETF

Principal Investments

According to the Registration Statement, the Fund's investment objective is to seek a high level of total return consisting of income and capital appreciation.

Under normal market conditions,[7] the Fund invests at least 80% of its net assets in a portfolio of mortgage-related fixed income instruments of varying maturities. The mortgage-related fixed income instruments in which the Fund may invest are the following: Residential mortgage-backed securities (''RMBS''); commercial mortgage-backed securities (''CMBS''); collateralized mortgage obligations (''CMOs''); stripped mortgage-backed securities; mortgage pass-through securities; and other securities representing an interest in or secured by or related to mortgages, including asset-backed securities (''ABS'').[8]

Under normal market conditions, the Fund will invest at least 80% of its net assets in mortgage-related securities issued by the U.S. government and its agencies, such as the Government National Mortgage Association (''GNMA'' or ''Ginnie Mae''), the Federal National Mortgage Association (''FNMA'' or ''Fannie Mae'') or the Federal Home Loan Mortgage Corporation (''FHLMC'' or ''Freddie Mac'').

The Fund may invest in exchange-traded funds (''ETFs'').[9]

The Fund will typically enter into ''to be announced'' or ''TBA'' commitments when purchasing mortgage-backed securities.

Other Investments

While the Fund, under normal market conditions, will invest at least 80% of its assets in agency mortgage-backed securities, the Fund may invest up to 20% of its assets in the securities and financial instruments described below.

The Fund may hold cash and cash equivalents.[10]

In addition to the securities described above under Principal Investments, the Fund may hold the following fixed income securities (''Fixed Income Securities''):

- U.S. government securities;
- industrial development bonds
- inflation-indexed bonds, including municipal inflation-indexed bonds and corporate inflation-indexed bonds; or in derivatives that are linked to these securities;
- municipal lease obligations;
- pass-through securities;
- variable and floating rate obligations (including ''inverse floaters);
- subordinated or junior debt;
- corporate bonds, debentures, notes, and other similar corporate debt instruments;
- non-agency, or privately-issued, residential and commercial mortgage-backed securities, and other mortgage-related securities.[11]

The Fund may enter into mortgage dollar rolls and may invest in to-be-announced transactions (''TBA'').

The Fund may enter into short sales of any securities in which the Fund may invest.

The Fund may hold the following listed derivative instruments: Futures, options (including options on futures), and swaps on commodities, currencies, U.S. and non-U.S. equity securities, fixed income securities as defined in Commentary .01(b) to Rule 8.600–E, interest rates, U.S. Treasuries, or a basket or index of any of the foregoing. Such listed derivatives will comply with the criteria in Commentary .01(d) of NYSE Arca Rule 8.600–E.

The Fund may hold the following over-the-counter (''OTC'') derivative instruments: Forwards, options, and OTC total return swaps on commodities, currencies, U.S. and non-U.S. equity securities, fixed income securities as defined in Commentary .01(b) to Rule 8.600–E, interest rates, or a basket or index of any of the foregoing. The Fund also may hold OTC credit default swaps.

The Fund may enter into OTC options on swap agreements (''swaptions'').

The Fund may invest in securities of non-exchange-traded investment company securities, subject to applicable limitations under Section 12(d)(1) of the 1940 Act.

[6] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[7] The term ''normal market conditions'' is defined in NYSE Arca Rule 8.600–E(c)(5).

[8] The Fund will typically invest in asset-backed securities backed by pools of home equity loans and other mortgage-related debt. Asset-backed securities are collateralized by pools of obligations or assets. Asset-backed securities may take the form of commercial paper, notes, or pass-through certificates and may be structured as floaters, inverse floaters, interest-only and principal-only obligations.

[9] For purposes of this filing, ''ETFs'' are Investment Company Units (as described in NYSE Arca Rule 5.2–E(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Rule 8.100–E); and Managed Fund Shares (as described in NYSE Arca Rule 8.600–E). All ETFs will be listed and traded in the U.S. on a national securities exchange.

[10] For purposes of this filing, cash equivalents include the securities included in Commentary .01(c) to NYSE Arca Rule 8.600–E.

[11] Non-agency, or privately-issued, residential and commercial MBS, and other mortgage-related securities and other asset-backed securities are referred to herein as ''Private ABS/MBS''.

The Fund may invest in private placements, restricted securities and Rule 144A securities.

The Fund will not invest in securities or other financial instruments that have not been described in this proposed rule change.

Other Restrictions

The Fund's investments, including derivatives, will be consistent with the Fund's investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).[12]

The Fund's Use of Derivatives

Investments in derivative instruments will be made in accordance with the Fund's investment objective and policies.

To limit the potential risk associated with such transactions, the Fund will enter into offsetting transactions or segregate or ''earmark'' assets determined to be liquid by the Adviser in accordance with procedures established by the Trust's Board of Trustees (the ''Board''). In addition, the Fund has included appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of the Fund, including the Fund's use of derivatives, may give rise to leverage, causing the Fund to be more volatile than if it had not been leveraged.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will issue and redeem Shares only in Creation Units of at least 25,000 Shares on a continuous basis at their NAV per Share next determined after receipt of an order on any business day. The size of a Creation Unit is subject to change. The consideration for purchase of Creation Units of the Fund generally consists of cash. If creations are not conducted in cash, the consideration for purchase of Creation Units of the Fund generally consists of the in-kind deposit of a designated portfolio of securities (including any portion of such securities for which cash may be substituted) (''Deposit Securities'') and the Cash Component computed as described below. Together, the Deposit Securities and the Cash Component constitute the ''Fund Deposit,'' which will be applicable to creation requests received in proper form. The Fund Deposit represents the minimum initial and subsequent investment amount for a Creation Unit of a Fund.

The ''Cash Component'' is an amount equal to the difference between the NAV of the Shares (per Creation Unit) and the ''Deposit Amount,'' which is an amount equal to the market value of the Deposit Securities, and serves to compensate for any differences between the NAV per Creation Unit and the Deposit Amount.

Janus Capital makes available through the National Securities Clearing Corporation (''NSCC'') on each business day prior to the opening of business on the Exchange, the list of names and the required number or par value of each Deposit Security and the amount of the Cash Component to be included in the current Fund Deposit (based on information as of the end of the previous business day for the Fund). Such Fund Deposit is applicable to purchases of Creation Units of Shares of the Fund until such time as the next-announced Fund Deposit is made available.

The Fund reserves the right to permit or require the substitution of a ''cash in lieu'' amount to be added to the Cash Component to replace any Deposit Security that may not be available in sufficient quantity for delivery or that may not be eligible for transfer through Depository Trust Company (''DTC'') or the Clearing Process (as discussed below). The Fund also reserves the right to permit or require a ''cash in lieu'' amount in certain circumstances, including circumstances in which (i) the delivery of the Deposit Security by the Authorized Participant (as described below) would be restricted under applicable securities or other local laws or (ii) the delivery of the Deposit Security to the Authorized Participant would result in the disposition of the Deposit Security by the Authorized Participant becoming restricted under applicable securities or other local laws, or in certain other situations.

Procedures for Creating Creation Units

To be eligible to place orders with the Distributor and to create a Creation Unit of the Fund, an entity must be: (i) A ''Participating Party,'' *i.e.,* a broker-dealer or other participant in the clearing process through the Continuous Net Settlement System of the NSCC (the ''Clearing Process'') or (ii) a DTC Participant, and must have executed an agreement with the Distributor, with respect to creations and redemptions of Creation Units (''Authorized Participant Agreement''). A Participating Party or DTC Participant who has executed an Authorized Participant Agreement is referred to as an ''Authorized Participant.'' Creation Units may be purchased only by or through a DTC Participant that has entered into an Authorized Participant Agreement with the Distributor.

Purchase Orders

To initiate an order for a Creation Unit, an Authorized Participant must submit to the Distributor or its agent an irrevocable order to purchase Shares of the Fund, in proper form, by the ''Cutoff Time'' (as defined below).

An Authorized Participant must submit an irrevocable order to purchase Shares of the Fund generally before 3:00 p.m. (''Cutoff Time''), Eastern time (''E.T.'') on any business day in order to receive that day's NAV. Purchase orders and redemption requests, if accepted by the Trust, will be processed based on the NAV next determined after such acceptance.

Redemption of Creation Units

Shares of the Fund may be redeemed by Authorized Participants only in Creation Units at their NAV next determined after receipt of a redemption request in proper form by the Transfer Agent or its agent and only on a business day.

Janus Capital will make available through the NSCC, prior to the opening of business on the Exchange (currently 9:30 a.m. E.T.) on each business day, the designated portfolio of securities (including any portion of such securities for which cash may be substituted) that will be applicable to redemption requests received in proper form on that day (''Fund Securities''), and an amount of cash (the ''Cash Amount,'' as described below). Fund Securities received on redemption may not be identical to Deposit Securities that are applicable to creations of Creation Units.

The redemption proceeds for a Creation Unit generally consist of Fund Securities, plus the Cash Amount, which is an amount equal to the difference between the net asset value of the Shares being redeemed, as next determined after the receipt of a redemption request in proper form, and the value of Fund Securities, less a redemption transaction fee.

The Trust may, in its sole discretion, substitute a ''cash in lieu'' amount to replace any Fund Security. The Trust also reserves the right to permit or

[12] The Fund's broad-based securities benchmark index will be identified in a future amendment to the Registration Statement following the Fund's first full calendar year of performance.

require a ''cash in lieu'' amount in certain circumstances. The amount of cash paid out in such cases will be equivalent to the value of the substituted security listed as a Fund Security. In the event that the Fund Securities have a value greater than the NAV of the Shares, a compensating cash payment equal to the difference is required to be made by or through an Authorized Participant by the redeeming shareholder. The Fund generally redeems Creation Units in Fund Securities, plus any Cash Amount due.

Cash Redemption Method

Although the Trust will not ordinarily permit partial or full cash redemptions of Creation Units of the Fund, when partial or full cash redemptions of Creation Units are available or specified they will be effected in essentially the same manner as in-kind redemptions thereof. In the case of partial or full cash redemption, the Authorized Participant receives the cash equivalent of the Fund Securities it would otherwise receive through an in-kind redemption, plus the same Cash Amount to be paid to an in-kind redeemer.[13]

Placement of Redemption Orders

Redemption requests for Creation Units of the Fund must be submitted to the Transfer Agent by or through an Authorized Participant. An Authorized Participant must submit an irrevocable request to redeem Shares of the Fund generally before 3:00 p.m., E.T. on any business day, in order to receive that day's NAV.

Disclosed Portfolio

The Fund's disclosure of derivative positions in the applicable Disclosed Portfolio includes information that market participants can use to value these positions intraday. On a daily basis, the Fund will disclose the information regarding the Disclosed Portfolio required under NYSE Arca Rule 8.600–E (c)(2) to the extent applicable. The Fund's website information will be publicly available at no charge.

Impact on Arbitrage Mechanism

The Adviser believes there will be minimal impact to the arbitrage mechanism as a result of the use of derivatives. Market makers and participants should be able to value derivatives as long as the positions are disclosed with relevant information. The Adviser believes that the price at which Shares trade will continue to be disciplined by arbitrage opportunities created by the ability to purchase or redeem Shares at their NAV, which should ensure that Shares will not trade at a material discount or premium in relation to their NAV.

The Adviser does not believe there will be any significant impacts to the settlement or operational aspects of the Fund's arbitrage mechanism due to the use of derivatives. Because derivatives generally are not eligible for in-kind transfer, they will typically be substituted with a ''cash in lieu'' amount when the Fund processes purchases or redemptions of creation units in-kind.

Application of Generic Listing Requirements

The Exchange is submitting this proposed rule change because the portfolio for the Fund will not meet all of the ''generic'' listing requirements of Commentary .01 to NYSE Arca Rule 8.600–E applicable to the listing of Managed Fund Shares. The Fund's portfolio would meet all such requirements except for those set forth in Commentary .01(a)[14] and Commentary .01(b)(4)[15] to NYSE Arca Rule 8.600–E.

The Fund will not comply with the requirements in Commentary .01(b)(4) to Rule 8.600–E that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria specified in Commentary .01(b)(4), because certain Private ABS/MBS by their nature cannot satisfy the criteria in Commentary .01(b)(4).[16] Instead, the Exchange proposes that the Fund's investments in Fixed Income Securities other than Private ABS/MBS will be required to comply with the requirements of Commentary .01(b)(4). The Exchange believes that excluding Private ABS/MBS from the 90% calculation in Commentary .01(b)(4) is consistent with the Act because the Fund's portfolio will minimize the risk to the overall Fund associated with any particular holding of the Fund as a result of the diversification provided by the investments and the Adviser's selection process, which closely monitors investments to ensure maintenance of credit and liquidity standards. Further, the Exchange believes that this alternative limitation is appropriate because Commentary .01(b)(4) to Rule 8.600–E is not designed for structured finance vehicles such as Private ABS/MBS.

The Exchange notes that the Commission has previously approved

[13] The Adviser represents that, to the extent the Trust effects the creation or redemption of Shares in cash on any given day, such transactions will be effected in the same manner for all Authorized Participants placing trades with the Fund on that day.

[14] Commentary .01(a) to Rule 8.600–E specifies the equity securities accommodated by the generic criteria in Commentary .01(a), namely, U.S. Component Stocks (as described in Rule 5.2–E(j)(3)) and Non-U.S. Component Stocks (as described in Rule 5.2–E(j)(3)). Commentary .01(a)(1) to Rule 8.600–E (U.S. Component Stocks) provides that the component stocks of the equity portion of a portfolio that are U.S. Component Stocks shall meet the following criteria initially and on a continuing basis:

(A) Component stocks (excluding Derivative Securities Products and Index-Linked Securities) that in the aggregate account for at least 90% of the equity weight of the portfolio (excluding such Derivative Securities Products and Index-Linked Securities) each shall have a minimum market value of at least $75 million;

(B) Component stocks (excluding Derivative Securities Products and Index-Linked Securities) that in the aggregate account for at least 70% of the equity weight of the portfolio (excluding such Derivative Securities Products and Index-Linked Securities) each shall have a minimum monthly trading volume of 250,000 shares, or minimum notional volume traded per month of $25,000,000, averaged over the last six months;

(C) The most heavily weighted component stock (excluding Derivative Securities Products and Index-Linked Securities) shall not exceed 30% of the equity weight of the portfolio, and, to the extent applicable, the five most heavily weighted component stocks (excluding Derivative Securities Products and Index-Linked Securities) shall not exceed 65% of the equity weight of the portfolio;

(D) Where the equity portion of the portfolio does not include Non-U.S. Component Stocks, the equity portion of the portfolio shall include a minimum of 13 component stocks; provided, however, that there shall be no minimum number of component stocks if (i) one or more series of Derivative Securities Products or Index-Linked Securities constitute, at least in part, components underlying a series of Managed Fund Shares, or (ii) one or more series of Derivative Securities Products or Index-Linked Securities account for 100% of the equity weight of the portfolio of a series of Managed Fund Shares; and

(E) Except as provided herein, equity securities in the portfolio shall be U.S. Component Stocks listed on a national securities exchange and shall be NMS Stocks as defined in Rule 600 of Regulation NMS under the Securities Exchange Act of 1934.

[15] Commentary .01(b)(4) provides that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio must be either: (a) From issuers that are required to file reports pursuant to Sections 13 and 15(d) of the Act; (b) from issuers that have a worldwide market value of its outstanding common equity held by non-affiliates of $700 million or more; (c) from issuers that have outstanding securities that are notes, bonds debentures, or evidence of indebtedness having a total remaining principal amount of at least $1 billion; (d) exempted securities as defined in Section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country.

[16] Private ABS/MBS are generally issued by special purpose vehicles in amounts smaller than the minimum dollar threshold set forth in Commentary .01(b)(4), so the criteria in Commentary .01(b)(4) to Rule 8.600–E regarding an issuer's market capitalization and the remaining principal amount of an issuer's securities are typically unavailable with respect to Private ABS/MBS, even though such Private ABS/MBS may own significant assets.

the listing of Managed Fund Shares with similar investment objectives and strategies without imposing requirements that a certain percentage of such funds' securities meet one of the criteria comparable to those set forth in Commentary .01(b)(4).[17]

The Fund may invest in non-exchange-traded investment company securities, which are equity securities. Because such securities have a net asset value based on the value of securities and financial assets the investment company holds, the Exchange believes it is both unnecessary and inappropriate to apply to such investment company securities the criteria in Commentary .01(a)(1).[18]

The Exchange notes that the Commission has previously approved the listing of Managed Fund Shares with similar investment objectives and strategies where such funds were permitted to invest in the shares of other registered investment companies that are not ETFs or money market funds.[19]

The Adviser represents that the proposed exceptions from the requirements of Commentary .01 to Rule 8.600–E described above are consistent with the Fund's investment objective, and will further assist the Adviser to achieve such investment objective. Deviations from the generic requirements are necessary for the Fund to achieve its investment objective in a manner that is cost-effective and that maximizes investors' returns. Further, the proposed alternative requirements are narrowly tailored to allow the Fund to achieve its investment objective in manner that is consistent with the principles of Section 6(b)(5) of the Act. As a result, it is in the public interest to approve listing and trading of Shares of the Fund on the Exchange pursuant to the requirements set forth herein.

The Exchange notes that, other than Commentary .01(a) and (b)(4) to Rule 8.600–E, as described above, the Fund's portfolio will meet all other requirements of Rule 8.600–E.

Availability of Information

The Fund's website (*www.janushenderson.com*), which is publicly available, includes a form of the prospectus for the Fund that may be downloaded. The Fund's website includes additional quantitative information updated on a daily basis, including, for the Fund, (1) daily trading volume, the prior business day's reported closing price, NAV and mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''),[20] and a calculation of the premium and discount of the Bid/Ask Price against the NAV, and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Adviser discloses on the Fund's website the Disclosed Portfolio for the Fund as defined in NYSE Arca Rule 8.600–E(c)(2) that will form the basis for the Fund's calculation of NAV at the end of the business day.[21]

Investors can also obtain the Trust's Statement of Additional Information (''SAI''), the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov.*

Quotation and last sale information for the Shares and ETFs will be available via the CTA high speed line. Price information for U.S. and foreign exchange-traded futures and options on futures will be available from the exchange on which they are listed. Quotation and last sale information for exchange-listed options cleared via the Options Clearing Corporation will be available via the Options Price Reporting Authority. Information regarding market price and trading volume for the Shares is continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares are published daily in the financial section of newspapers.

Quotation information for RMBS, CMBS, CMOs, ABS, OTC options, cash equivalents, swaps, swaptions, and Fixed Income Securities may be obtained from brokers and dealers who make markets in such securities or through nationally recognized pricing services through subscription agreements. Price information for OTC derivative instruments, OTC credit default swaps, 144A securities, private placement securities and restricted securities is available from major market data vendors.

In addition, the Portfolio Indicative Value (''PIV''), as defined in NYSE Arca Rule 8.600–E(c)(3), is widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session.[22] The dissemination of the PIV, together with the Disclosed Portfolio, allows investors to determine the approximate value of the underlying portfolio of the Fund on a daily basis and provides a close estimate of that value throughout the trading day.

[17] *See, e.g.,* Exchange Act Release Nos. 67894 (September 20, 2012), 77 FR 59227 (September 26, 2012) (SR–BATS–2012–033) (order approving the listing and trading of shares of the iShares Short Maturity Bond Fund); 70342 (September 6, 2013), 78 FR 56256 (September 12, 2013) (SR–NYSEArca–2013–71) (order approving the listing and trading of shares of the SPDR SSgA Ultra Short Term Bond ETF, SPDR SSgA Conservative Ultra Short Term Bond ETF and SPDR SSgA Aggressive Ultra Short Term Bond ETF). *See also,* Securities Exchange Act Release Nos. 84047 (September 6, 2018), 83 FR 46200 (September 12, 2018) (SR–NASDAQ–2017–128) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, to List and Trade Shares of the Western Asset Total Return ETF); 85022 (January 31, 2019), 25 FR 2265 (February 6, 2019) (SR–NASDAQ–2018–080) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1, 2 and 3, To List and Trade Shares of the BrandywineGLOBAL-Global Total Return ETF).

[18] The Commission has previously approved proposed rule changes under Section 19(b) of the Act for series of Managed Fund Shares that may invest in non-exchange traded investment company securities. *See, e.g.,* Securities Exchange Act Release No. 85244 (March 4, 2019), 84 FR 8553 (March 8, 2019) (SR–NYSEArca–2018–82) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, Regarding Certain Changes Relating to Investments of the PGIM Active High Yield Bond ETF).

[19] *See, e.g.,* Securities Exchange Act Release Nos. 79053 (October 5, 2016), 81 FR 70468 (October 12, 2016) (SR–BatsBZX–2016–35) (permitting the JPMorgan Global Bond Opportunities ETF to invest in ''investment company securities that are not ETFs''); 74297 (February 18, 2015), 80 FR 9788 (February 24, 2015) (SR–BATS–2014–056) (permitting the U.S. Fixed Income Balanced Risk ETF to invest in ''exchange traded and non-exchange traded investment companies (including investment companies advised by the Adviser or its affiliates) that invest in such Fixed Income Securities''); 83319 (May 24, 2018), 83 FR 25097 (May 31, 2018) (SR–NYSEArca–2018–15), (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to Continue Listing and Trading Shares of the PGIM Ultra Short Bond ETF under NYSE Arca Rule 8.600–E).

[20] The Bid/Ask Price of the Fund's Shares will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices are retained by the Fund and/or its service providers.

[21] Under accounting procedures to be followed by the Fund, trades made on the prior business day (''T'') are booked and reflected in NAV on the current business day (''T+1''). Accordingly, the Fund is able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[22] Currently, it is the Exchange's understanding that several major market data vendors display and/or make widely available PIVs taken from the CTA or other data feeds.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.[23] Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares of the Fund inadvisable.

Trading in the Shares will be subject to NYSE Arca Rule 8.600–E(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

Trading Rules

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. Shares will trade on the NYSE Arca Marketplace from 4:00 a.m. to 8:00 p.m. E.T. in accordance with NYSE Arca Rule 7.34–E (Early, Core, and Late Trading Sessions). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Except as described herein, the Shares of the Fund will conform to the continued listing criteria under NYSE Arca Rule 8.600–E. The Exchange represents that, for continued listing, the Fund will be in compliance with Rule 10A–3 [24] under the Act, as provided by NYSE Arca Rule 5.3–E. The Exchange has obtained a representation from the issuer of the Shares of the Fund that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.

Surveillance

The Exchange represents that trading in the Shares is subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[25] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, ETFs, certain futures, and certain exchange-traded options with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities and financial instruments from such markets and other entities. In addition, the Exchange may obtain information regarding trading in such securities and financial instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[26] FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's Trade Reporting and Compliance Engine (''TRACE'').

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio holdings or reference asset, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares on the Exchange.

The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

The Exchange will inform its Equity Trading Permit (''ETP'') Holders in an Information Bulletin (''Bulletin'') of the special characteristics and risks associated with trading the Shares of the Fund. Specifically, the Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) NYSE Arca 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) the risks involved in trading the Shares during the Early and Late Trading Sessions when an updated PIV will not be calculated or publicly disseminated; (4) how information regarding the PIV and the Disclosed Portfolio is disseminated; (5) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Bulletin will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Bulletin will discuss any exemptive, no-action, and interpretive relief granted by the Commission from any rules under the Act. The Bulletin will also disclose that the NAV for the Shares of the Fund will be calculated after 4:00 p.m. E.T. each trading day.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [27] that an exchange have rules that are 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, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will

[23] *See* NYSE Arca Rule 7.12–E.

[24] 17 CFR 240 10A–3.

[25] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[26] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[27] 15 U.S.C. 78f(b)(5).

be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.600–E. The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a fire wall with respect to such broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio. The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares, ETFs, certain futures, and certain exchange-traded options with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading such securities and financial instruments from such markets and other entities. In addition, the Exchange may obtain information regarding trading in such securities and financial instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.

Except as described herein, the Shares of the Fund will conform to the continued listing criteria under NYSE Arca Rule 8.600–E. The Exchange represents that, for continued listing, the Fund will be in compliance with Rule 10A–3 under the Act, as provided by NYSE Arca Rule 5.3–E. The Exchange has obtained a representation from the issuer of the Shares of the Fund that the NAV per Share is calculated daily and that the NAV and the Disclosed Portfolio are made available to all market participants at the same time. In addition, a large amount of information is publicly available regarding the Fund and the Shares, thereby promoting market transparency. The Fund's portfolio holdings are disclosed on its website daily after the close of trading on the Exchange and prior to the opening of trading on the Exchange the following day. On a daily basis, the Fund discloses the information regarding the Disclosed Portfolio required under NYSE Arca Rule 8.600–E (c)(2) to the extent applicable. The Fund's website information is publicly available at no charge.

Investors can also obtain the Trust's SAI, the Fund's Shareholder Reports, and its Form N–CSR and Form N–SAR, filed twice a year. The Trust's SAI and Shareholder Reports are available free upon request from the Trust, and those documents and the Form N–CSR and Form N–SAR may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov*.

The website for the Fund includes a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of the Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to NYSE Arca Rule 8.600–E(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors have ready access to information regarding the Fund's holdings, the PIV, the Disclosed Portfolio, and quotation and last sale information for the Shares. The Fund's investments, including derivatives, will be consistent with the Fund's investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).

With respect to the Fund's investment in Private ABS/MBS, the proposed non-compliance with the requirements in Commentary .01(b)(4) to Rule 8.600–E that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria specified in Commentary .01(b)(4) is appropriate because certain Private ABS/MBS by their nature cannot satisfy the criteria in Commentary .01(b)(4). Instead, the Exchange proposes that the Fund's investments in Fixed Income Securities other than Private ABS/MBS will be required to comply with the requirements of Commentary .01(b)(4), and Private ABS/MBS will be limited to 20% of the weight of the Fund's portfolio. The Exchange believes that excluding Private ABS/MBS from the 90% calculation in Commentary .01(b)(4) is consistent with the Act because the Fund's portfolio will minimize the risk to the overall Fund associated with any particular holding of the Fund as a result of the diversification provided by the investments and the Adviser's selection process, which closely monitors investments to ensure maintenance of credit and liquidity standards. Further, the Exchange believes that this alternative limitation is appropriate because Commentary .01(b)(4) to Rule 8.600–E is not designed for structured finance vehicles such as Private ABS/MBS.

The Exchange notes that the Commission has previously approved the listing of Managed Fund Shares with similar investment objectives and strategies without imposing requirements that a certain percentage of such funds' securities meet one of the criteria set forth in Commentary .01(b)(4).[28]

The Fund may invest in shares of non-exchange-traded open-end management investment company securities, which are equity securities. Therefore, the Fund will not comply with the requirements of Commentary .01(a)(1) to NYSE Arca Rule 8.600–E (U.S. Component Stocks) with respect to its equity securities holdings. It is appropriate and in the public interest to approve listing and trading of Shares of the Fund notwithstanding that the Fund's holdings in such securities would not meet the requirements of Commentary .01(a)(1)(A) through (E) to Rule 8.600–E. The Fund's investment in shares of non-exchange-traded open-end management investment company securities will be utilized in order to obtain income on short-term cash balances while awaiting attractive investment opportunities, to provide liquidity in preparation for anticipated redemptions or for defensive purposes, which will allow the Fund to obtain the benefits of a more diversified portfolio available in the shares of non-exchange-traded open-end management investment company securities than might otherwise be available. Moreover, such investments, which may include mutual funds that invest, for example, principally in fixed income securities,

[28] *See* note 17, *supra.*

would be utilized to help the Fund meet its investment objective and to equitize cash in the short term. The Fund will invest in such securities only to the extent that those investments would be consistent with the requirements of Section 12(d)(1) of the 1940 Act and the rules thereunder. Because such securities must satisfy applicable 1940 Act diversification requirements, and have a net asset value based on the value of securities and financial assets the investment company holds, it is both unnecessary and inappropriate to apply to such investment company securities the criteria in Commentary .01(a)(1).

The Exchange notes that it would be difficult or impossible to apply to mutual fund shares certain of the generic quantitative criteria (*e.g.,* market capitalization, trading volume, or portfolio criteria) in Commentary .01 (A) through (D) applicable to U.S. Component Stocks. For example, the requirements for U.S. Component Stocks in Commentary .01(a)(1)(B) that there be minimum monthly trading volume of 250,000 shares, or minimum notional volume traded per month of $25,000,000, averaged over the last six months are tailored to exchange-traded securities (*i.e.,* U.S. Component Stocks) and not to mutual fund shares, which do not trade in the secondary market and for which no such volume information is reported. In addition, Commentary .01(a)(1)(A) relating to minimum market value of portfolio component stocks, Commentary .01(a)(1)(C) relating to weighting of portfolio component stocks, and Commentary .01(a)(1)(D) relating to minimum number of portfolio components are not appropriately applied to open-end management investment company securities; open-end investment companies hold multiple individual securities as disclosed publicly in accordance with the 1940 Act, and application of Commentary .01(a)(1)(A) through (D) would not serve the purposes served with respect to U.S. Component Stocks, namely, to establish minimum liquidity and diversification criteria for U.S. Component Stocks held by series of Managed Fund Shares.

The Exchange accordingly believes that it is appropriate and in the public interest to approve listing and trading of Shares of the Fund on the Exchange notwithstanding that the Fund would not meet the requirements of Commentary .01(a)(1)(A) through (D) and (b)(4) to Rule 8.600–E. The Exchange notes that, other than Commentary .01(a)(1) and (b)(4) to Rule 8.600–E, the Fund's portfolio will meet all other requirements of Rule 8.600–E.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that principally holds fixed income securities and derivatives and that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares of the Fund and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors have ready access to information regarding the Fund's holdings, the PIV, the Disclosed Portfolio for the Fund, and quotation and last sale information for the Shares of the Fund.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change will facilitate the listing and trading of an additional type of actively-managed exchange-traded product that principally holds fixed income securities and derivatives and that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2019–51 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2019–51. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2019–51 and

should be submitted on or before August 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15774 Filed 7–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–86416; File No. SR–NASDAQ–2019–044]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Order Approving a Proposed Rule Change To Allow an Odd Lot-Sized Order To Be Eligible for the Midpoint Extended Life Order

July 19, 2019.

I. Introduction

On May 20, 2019, The Nasdaq Stock Market LLC (''Exchange'' or ''Nasdaq'') 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 allow an odd lot-sized order to be eligible for the Midpoint Extended Life Order (''MELO''). The proposed rule change was published for comment in the **Federal Register** on June 4, 2019.[3] The Commission received no comment letters on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposal

The Exchange proposes to allow an odd lot-sized order [4] to be eligible for MELO.[5] MELO is an order type with a non-display order attribute that is priced at the midpoint between the National Best Bid and National Best Offer (''NBBO'') and that will not be eligible to execute until a holding period of one-half second has passed after acceptance of the order by the system. Once a MELO becomes eligible to execute, the order may only execute against other eligible MELOs.

Currently, a MELO must be entered with a size of at least one round lot and any shares of a MELO remaining after an execution that are less than a round lot will be cancelled by the system.[6] According to the Exchange, the number of high-priced securities has increased over the last several years and there is a notably large percentage of odd lot trades in relatively high-priced securities.[7] The Exchange proposes to allow odd lot-sized MELOs in order to provide additional trading opportunities for the order type, particularly in high-priced securities.

The Exchange notes that any participants using MELOs that do not wish to execute in odd lots may elect to use the minimum quantity order attribute with their MELOs to avoid such transactions, as they may currently do for other executions on the Nasdaq book.[8] The Exchange further notes that, because use of the minimum quantity order attribute is limited to orders of at least one round lot upon entry,[9] members entering odd lot-sized MELOs would not be able to use this order attribute to limit their interaction with other odd lot-sized MELOs based on size.[10] Moreover, the Exchange notes that most of the other order types under Nasdaq Rule 4702 allow the entry of odd lot-sized orders.[11]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[12] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[13] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

In its original order approving MELO on the Exchange, the Commission noted its belief that the MELO order type could create additional and more efficient trading opportunities on the Exchange for investors with longer investment time horizons, including institutional investors, and could provide these investors with an ability to limit the information leakage and the market impact that could result from their orders.[14] While MELO use on the Exchange is currently limited to orders entered with a size of at least one round lot and any shares of a MELO remaining after an execution that are less than a round lot are cancelled by the system, the Commission believes the Exchange's proposal to allow odd lot-sized orders to be eligible for MELO could create additional opportunities for investors to utilize the order type consistent with the intended purpose of the order type and could create greater opportunities for interactions in MELOs, particularly in high-priced securities. The Commission also believes that the ability to use the minimum quantity order attribute would provide Nasdaq members entering round lot-sized MELOs with additional control over the execution of their MELOs, including allowing members to avoid trading with odd lot-sized MELOs.[15]

Based on the foregoing, the Commission finds that the proposed rule change is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[16] that the proposed rule change (SR–NASDAQ–2019–044) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2019–15773 Filed 7–24–19; 8:45 am]

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[29] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85954 (May 29, 2019), 84 FR 25844 (''Notice'').

[4] The terms ''normal unit of trading'' or ''round lot'' mean the size generally employed by traders when trading a particular security, which is 100 shares in most instances. The term ''odd lot'' means a size of less than one normal unit of trading. *See* Nasdaq Rule 4703(b).

[5] *See* Nasdaq Rule 4702(b)(14).

[6] *See* Nasdaq Rule 4702(b)(14)(B).

[7] *See* Notice, *supra* note 3, at 25845–46. See also *id.* at 25845–47, for more specific data provided by the Exchange to support its assertions.

[8] *See id.* at 25847.

[9] *See* Nasdaq Rule 4703(e).

[10] *See* Notice, *supra* note 3, at 25847.

[11] *See id.*

[12] 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).

[13] 15 U.S.C. 78f(b)(5).

[14] *See* Securities Exchange Act Release No. 82825 (March 7, 2018), 83 FR 10937, 10938–39 (March 13, 2018) (order approving SR–NASDAQ–2017–074).

[15] As noted above, members who choose to enter odd lot-sized MELOs would be unable to use the minimum quantity order attribute with such orders because the minimum quantity order attribute is limited to orders with a size of at least one round lot upon entry. *See supra* notes 9–10 and accompanying text.

[16] 15 U.S.C. 78s(b)(2).

[17] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[License No. 03/03–0254]

Renovus Capital Partners, L.P.; Notice Seeking Exemption Under the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Renovus Capital Partners, L.P., 460 East Swedesford Road, Suite 2050, Wayne, PA 19087, 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).

The financing is brought within the purview of § 107.730(a) of the SBIC Regulations because Renovus Capital Partners, L.P. proposes to seeks to merge two portfolio companies Prime Technology Group, LLC, 1006 W 9th Ave., Suite 150, King of Prussia, PA 19406 and Image Process Design, LLC, 36800 Woodward Ave., Suite 300, Bloomfield Hills, MI 48304. Both companies are Associates of Renovus Capital Partners, L.P. due to its majority ownership of each company.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

A. Joseph Shepard,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2019–15842 Filed 7–24–19; 8:45 am]

BILLING CODE P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36329]

Bucyrus Industrial Railroad, LLC—Operation Exemption—Bucyrus Railcar Repair, LLC

Bucyrus Industrial Railroad, LLC (BIR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate, pursuant to an agreement with Bucyrus Railcar Repair, LLC (BRR),[1] approximately 26,400 feet (5.0 miles) of track owned by BRR in Bucyrus, Ohio (the Line), which connects to a Norfolk Southern Railway Company line.

According to BIR, there are no mileposts on the Line. BIR states that, pursuant to an operating agreement with BRR, BIR would provide common carrier rail service over the Line, which would include the provision of rail service to BRR, as well as bulk transloading and container transfer services to the public.

BIR states that the Line is currently operated by BRR as excepted track under 49 U.S.C. 10906. However, because BIR will operate the Line as its entire line of railroad, it asserts that it will become a rail carrier upon consummation of the proposed transaction. *See Effingham R.R.—Pet. for Declaratory Order—Constr. at Effingham, Ill.,* 2 S.T.B. 606, 609–10 (1997), aff'd sub nom. *United Transp. Union-Ill. Legislative Bd.* v. *STB,* 183 F.3d 606 (7th Cir. 1999).

BIR certifies that its projected annual revenues as a result of this transaction would not exceed those that would qualify it as a Class III rail carrier and would not exceed $5 million. BIR also certifies that its proposed operation does not involve a provision or agreement that may limit future interchange with a third-party connecting carrier.

The transaction may be consummated on or after August 8, 2019, the effective date of the exemption (30 days after the verified notice of exemption was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than August 1, 2019 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36329, must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on BIR's representative, David F. Rifkind, Stinson LLP, 1775 Pennsylvania Ave. NW, Suite 800, Washington, DC 20006.

According to BIR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: July 17, 2019.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2019–15829 Filed 7–24–19; 8:45 am]

BILLING CODE 4915–01–P

[1] BIR states that BIR and BRR are affiliates under common ownership by Cathcart Rail, LLC, a noncarrier.

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36095]

Palmetto Railways—Construction and Operation Exemption—in Berkeley County, SC

AGENCY: Surface Transportation Board.

ACTION: Notice of construction and operation exemption.

SUMMARY: The Board is granting an exemption from the prior approval requirements for Palmetto Railways to construct and operate a new rail line in Berkeley County, SC (the Line). The Line will be used to provide rail service to Volvo Cars of North America and other potential shippers in the Camp Hall Commerce Park. This exemption is subject to environmental mitigation conditions.

DATES: The exemption will be effective on August 21, 2019; petitions to reconsider must be filed by August 12, 2019.

ADDRESSES: All pleadings, referring to Docket No. FD 36095, must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, each filing in this proceeding must be served on Palmetto Railways' representative: Chad N. Johnston, Willoughby & Hoefer, P.A., 133 River Landing Drive, Suite 200, Charleston, SC 29492.

FOR FURTHER INFORMATION CONTACT: Sarah Fancher at (202) 245–0355. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision served on July 22, 2019, which is available at *www.stb.gov.*

By the Board, Board Members Begeman, Fuchs, and Oberman.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2019–15803 Filed 7–24–19; 8:45 am]

BILLING CODE 4915–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2019–0007]

Request for Comments on Operation of the Caribbean Basin Initiative

AGENCY: Office of the United States Trade Representative.

ACTION: Notice and request for comments.

SUMMARY: The U.S. Trade Representative has to submit a report to Congress regarding the operation of the Caribbean Basin Initiative (CBI) by December 31, 2019. The Trade Policy Staff Committee (TPSC) invites comments concerning the operation of the CBI, including the performance of each beneficiary country, to assist in preparing the report to Congress on the operation of the CBI program.

DATES: The TPSC must receive your written comments by August 30, 2019.

ADDRESSES: The TPSC strongly prefers electronic submissions made through the Federal Rulemaking Portal: *https://www.regulations.gov,* using docket number USTR–2019–0007. Follow the instructions for submitting comments in ''Requirements for Submissions'' below. For alternatives to on-line submissions, please contact Magaly Garcia, Director for Bolivia, Ecuador, and the Caribbean, at *magaly.a.garcia@ustr.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Please contact Magaly Garcia, Director for Bolivia, Ecuador, and the Caribbean, at *magaly.a.garcia@ustr.eop.gov,* or 202–395–9539.

SUPPLEMENTARY INFORMATION:

I. Background

Together, the Caribbean Basin Economic Recovery Act (CBERA), as amended by the Caribbean Basin Trade Partnership Act (CBTPA) (19 U.S.C. 2701 *et seq.*), are commonly referred to as the Caribbean Basin Initiative, or CBI. Section 212(f)(1) of CBERA (19 U.S.C. 2702(f)(1)) requires the U.S. Trade Representative to report on the performance of each CBERA or CBTPA beneficiary country. Barbados, Belize, Curacao, Guyana, Haiti, Jamaica, Saint Lucia, and Trinidad and Tobago receive benefits under both CBERA and CBTPA. Antigua and Barbuda, Aruba, the Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, Saint Kitts and Nevis, and Saint Vincent and the Grenadines currently receive benefits only under CBERA. For the purposes of this report, the term ''beneficiary country'' includes both the independent countries and dependent territories receiving benefits under CBTPA and/or CBERA.

As described in more detail below, the TPSC seeks comments on any aspect of the CBI program's operation, including the performance of CBERA and CBTPA beneficiary countries under the criteria described in sections 212(b) (19 U.S.C. 2702(b)), 212(c) (19 U.S.C. 2702(c)), and 213(b)(5)(B) (19 U.S.C. 2703(b)(5)(B)) of the CBERA, as amended. You can access the criteria at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title19/html/USCODE-2011-title19-chap15.htm*. The report also will examine the CBI's effect on the volume and composition of trade and investment between the United States and the CBI beneficiary countries and on advancing U.S. trade policy goals. You can access the most recent CBI report at: *https://ustr.gov/sites/default/files/gsp/2017%20CBI%20Report.pdf*.

II. Reporting Requirements on the Eligibility Criteria for All CBI Beneficiary Countries

The TPSC seeks comments on any aspect of the CBI program's operation, including the performance of CBERA and CBTPA beneficiary countries using the following criteria:

A. CBERA: Bases for Ineligibility

Under section 212(b) (19 U.S.C. 2702(b)), unless the President determines that it is in the national economic or security interest of the United States, the President may not designate as a CBI beneficiary country any country that:

1. Is a Communist country.

2. Has expropriated, nationalized, or otherwise seized control of property owned by a U.S. citizen or by a corporation which is 50 percent or more owned by a U.S. citizen, unless the President determines that the country is taking steps to resolve the U.S. citizen's claim.

3. Fails to act in good faith in recognizing as binding or in enforcing arbitral awards in favor of U.S. citizens or corporations owned by U.S. citizens.

4. Affords preferential treatment to the products of a developed country other than the United States that has, or is likely to have, a significant adverse effect on U.S. commerce, unless the President has received satisfactory assurances that the country will eliminate the preferential treatment or acts to assure that there will be no significant adverse effect.

5. Allows a government-owned entity in such country to engage in the broadcast of copyrighted material, including films or television material, belonging to United States copyright owners without their express consent.

6. Is not a signatory to a treaty, convention, protocol, or other agreement regarding the extradition of U.S. citizens.

7. Has not or is not taking steps to afford internationally recognized worker rights, as defined in section 507(4) of the Trade Act of 1974, as amended (19 U.S.C. 2467(4)), to workers in the country (including any designated zone in that country).

B. CBERA: Factors Determining Designation

Under section 212(c) (19 U.S.C. 2702(c)), the President has to consider the following factors in determining whether to designate any country as a CBI beneficiary country:

1. An expression of a country's desire to be so designated.

2. The economic conditions and living standards in a country.

3. The extent to which a country has assured the United States that it will provide equitable and reasonable access to the markets and basic commodity resources of the country.

4. The degree to which the country follows the international trade rules of the World Trade Organization (WTO).

5. The degree to which a country uses export subsidies or imposes export performance requirements or local content requirements that distort international trade.

6. The degree to which the trade policies of a country as they relate to other beneficiary countries are contributing to the revitalization of the region.

7. The degree to which a country is undertaking self-help measures to promote its own economic development.

8. Whether or not a country has taken or is taking steps to afford to workers in that country (including any designated zone in that country) internationally recognized worker rights.

9. The extent to which a country provides adequate and effective legal means for foreign nationals to secure, exercise, and enforce exclusive intellectual property rights.

10. The extent to which a country prohibits its nationals from broadcasting U.S. copyrighted materials, including film and television material, without their express consent.

11. The extent to which a country cooperates with the United States in the administration of CBI preferences.

C. CBTPA: Eligibility Criteria

Under section 213(b)(5)(B) (19 U.S.C. 2703(b)(5)(B)), in considering the

eligibility of the CBI countries and dependent territories that have expressed an interest in receiving the enhanced preferences of the CBTPA, the President must take into account the existing eligibility criteria of the CBERA, as well as several additional revised criteria elaborated in the CBTPA. These additional criteria are:

1. Whether the beneficiary country has demonstrated a commitment to undertake its obligations under the World Trade Organization (WTO) on or ahead of schedule and participate in negotiations toward the completion of the Free Trade Area of the Americas (FTAA) or another free trade agreement.

2. The extent to which the country provides protection of intellectual property rights consistent with or greater than the protection afforded under the Agreement on Trade-Related Aspects of Intellectual Property Rights.

3. The extent to which the country provides internationally recognized worker rights, including: The right of association; the right to organize and bargain collectively; a prohibition on the use of any form of forced or compulsory labor; a minimum age for the employment of children; and acceptable conditions of work with respect to minimum wages, hours of work, and occupational safety and health.

4. Whether the country has implemented its commitments to eliminate the worst forms of child labor, as defined in section 507(6) of the Trade Act of 1974, as amended (19 U.S.C. 2467(6)).

5. The extent to which the country has met U.S. counter-narcotics certification criteria under the Foreign Assistance Act of 1961.

6. The extent to which the country has taken steps to become a party to and implements the Inter-American Convention Against Corruption.

7. The extent to which the country applies transparent, nondiscriminatory, and competitive procedures in government procurement, and contributes to efforts in international fora to develop and implement international rules on transparency in government procurement.

III. Requirements for Submissions

The TPSC must receive your comments by the August 30, 2019 deadline. You must make all submissions in English via *http://www.regulations.gov,* using Docket Number USTR–2019–0007. USTR will not accept hand-delivered submissions.

To make a submission using *http://www.regulations.gov,* enter the appropriate docket number in the ''search for'' field on the home page and click ''search.'' The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting ''notice'' under ''document type'' in the ''filter results by'' section on the left side of the screen and click on the link entitled ''comment now.'' You must identify on the first page of the submission the subject matter of the comment as the ''CBI Report to Congress.'' The *regulations.gov* website offers the option of providing comments by filling in a ''type comment'' field or by attaching a document using the ''upload file(s)'' field. The TPSC prefers that you provide submissions in an attached document and note ''see attached'' in the ''type comment'' field on the online submission form.

The TPSC prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf) format. If the submission is in another file format, please indicate the name of the software application in the ''Type Comment'' field. File names should reflect the name of the person or entity submitting the comments. Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the comment itself, rather than submitting them as separate files. Submissions should not exceed 30 single-spaced, standard letter-size pages in 12-point type, including attachments.

You will receive a tracking number upon completion of the submission procedure at *http://www.regulations.gov*. The tracking number is confirmation that *regulations.gov* received the submission. Keep the confirmation for your records. The TPSC is not able to provide technical assistance for the website. The TPSC may not consider documents you do not submit in accordance with these instructions. If you are unable to provide submissions as requested, please contact Magaly Garcia, Director for Bolivia, Ecuador, and the Caribbean, at *magaly.a.garcia@ustr.eop.gov,* to arrange for an alternative method of transmission.

IV. Business Confidential Submissions

If you ask the TPSC to treat information you submitted as business confidential information (BCI), you must certify that the information is business confidential and you would not customarily release it to the public. You must clearly designate BCI by marking the submission ''BUSINESS CONFIDENTIAL'' at the top and bottom of the cover page and each succeeding page, and indicating, via brackets, the specific information that is BCI. Additionally, you must include ''Business Confidential'' in the ''type comment'' field. For any submission containing BCI, you must separately submit a non-confidential version, *i.e.,* not as part of the same submission with the confidential version, indicating where BCI has been redacted. The TPSC will post the non-confidential version in the docket and it will be open to public inspection.

V. Public Viewing of Review Submissions

The TPSC will post comments in the docket for public inspection, except business confidential information. You can view comments on the *www.regulations.gov* website by entering the relevant docket number in the search field on the home page. You can find general information about the Office of the United States Trade Representative on its website: *http://www.ustr.gov*.

Edward Gresser,

Chair of the Trade Policy Staff Committee, Office of the United States Trade Representative.

[FR Doc. 2019–15764 Filed 7–24–19; 8:45 am]

BILLING CODE 3290–F9–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2019–0024]

Agency Information Collection Activities: Notice of Request for Approval of a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for approval of a new information collection.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a new information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on May 3, 2019. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by August 26, 2019.

ADDRESSES: You may send comments within 30 days to the Office of

Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention DOT Desk Officer. You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. All comments should include the Docket No. FHWA–2019–0024.

FOR FURTHER INFORMATION CONTACT: Damaris Santiago, 202–366–2034, Department of Transportation, FHWA, Office of Project Development and Environmental Review, E76–201, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: FHWA Environmental Excellence Awards.

Background: In 1995 FHWA established the biennial Environmental Excellence Awards to recognize partners, projects, and processes that use FHWA funding sources to go beyond environmental compliance and achieve environmental excellence. The Environmental Excellence Awards also recognize partners, projects, and processes that exemplify innovation and commitment to the human environment, and organization and process innovation. Awardees must make an outstanding contribution that goes beyond traditional transportation projects and that encourages environmental stewardship and partnerships to achieve a truly multi-faceted, environmentally sensitive transportation solution.

Award: Anyone can nominate a project, process, person or group that has used FHWA funding sources to make an outstanding contribution to transportation and the environment. The nominator is responsible for submitting an application via the FHWA Environmental Excellence Awards website that gives a summary of the outstanding accomplishments of the entry. The collected information will be used by FHWA to evaluate the project, showcase environmental excellence, and enhance the public's knowledge of environmental stewardship in the planning and project development process. Nominations will be reviewed by a panel of judges from varying backgrounds. It is anticipated that awards will be given every 2 years. The winners are presented plaques at an awards ceremony.

Respondents: Anyone who has used FHWA funding sources in the 50 States, U.S. territories, and the District of Columbia.

Frequency: The information will be collected biennially.

Estimated Average Burden per Response: 8 hours per respondent per application.

Estimated Total Annual Burden Hours: It is expected that the respondents will complete approximately 150 applications for an estimated total of 1200 annual burden hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, 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.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: July 16, 2019.

Michael Howell,

Information Collection Officer.

[FR Doc. 2019–15512 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0015]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel BETTINA VITA (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 26, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0115 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0115 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0115, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel BETTINA VITA is:

—*Intended Commercial Use of Vessel:* ''Coastwise Charter for 6 Passengers or less''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, South Carolina, North Carolina, Virginia, Delaware, New Jersey, New York, Rhode Island'' (Base of Operations: Miami, FL)

—*Vessel Length and Type:* 73′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0115 at *http://www.regulations.gov.* Interested parties

may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0115 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: July 22, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–15804 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0117]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel DELPHINE (Sailing Catamaran); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 26, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0117 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0117 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0117, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel DELPHINE is:

—*Intended Commercial Use of Vessel:* ''Chartering. Mostly day charters for private parties. Possibility of some overnight charters. Planning on starting as an uninspected passenger vessel carrying no more than 6 passengers. May go through Coast Guard inspection process to get certified for more than six people. 12 person capacity is based on builder's certification plaque. Coast Guard COI may be different.''

—*Geographic Region Including Base of Operations:* ''Rhode Island, New York (excluding New York Harbor), Connecticut, Massachusetts, Florida'' (Base of Operations: Newport, RI)

—*Vessel Length and Type:* 50′ sailing catamaran

The complete application is available for review identified in the DOT docket as MARAD–2019–0117 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part

388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2019–0117 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: July 22, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–15805 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0120]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PELAGIC 1 (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 26, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0120 by any one of the following methods:

- *Federal eRulemaking Portal:* **Federal Register** Go to *http://www.regulations.gov.* Search MARAD–2019–0120 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0120, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel PELAGIC 1 is:

—*Intended Commercial Use of Vessel:* ''Sport fishing''
—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, CA)
—*Vessel Length and Type:* 28′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0120 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised

that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0120 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: July 22, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–15808 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0119]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel KATHRYN JEAN (Sailing Catamaran); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 26, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0119 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0119 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0119, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel KATHRYN JEAN is:

—*Intended Commercial Use of Vessel:* ''Harbor and coastal cruises for no more than 12 passengers departing primarily from Marina Del Rey, CA. Skippered and bareboat charters.''

—*Geographic Region Including Base of Operations:* ''Washington, California, Alaska (excluding Southeast Alaska)'' (Base of Operations: Marina Del Ray, CA)

—*Vessel Length and Type:* 40′ sailing catamaran.

The complete application is available for review identified in the DOT docket as MARAD–2019–0119 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search

MARAD–2019–0119 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: July 22, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–15807 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0116]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel FOOTLOOSE (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 26, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2019–0116 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2019–0116 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2019–0116, 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.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel FOOTLOOSE is:

—*Intended Commercial Use of Vessel:* ''Private Vessel Charters, Passengers Only''

—*Geographic Region Including Base of Operations:* ''Florida, Georgia, North Carolina, South Carolina, Virginia'' (Base of Operations: Ormond Beach, FL)

—Vessel Length and Type: 81′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2019–0116 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2019–0116 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: July 22, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–15806 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Number NHTSA–2019–0027]

Agency Information Collection Activities; Notice and Request for Comments; State Notification to Consumers of Motor Vehicle Recall Status

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on May 7, 2019. No comments were received.

DATES: Comments must be submitted on or before August 26, 2019.

ADDRESSES: Send comments regarding the burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Attention: Desk Office for the Office of the Secretary of Transportation, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Alexander Ansley, Program Support Division, Office of Defects Investigation (NEF–110), (202) 493–0481, National Highway Traffic Safety Administration, Department of Transportation, 1200 New Jersey Avenue SE, W48–336, Washington, DC 20590. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation at 5 CFR 1320.8(d), an agency must ask for public comment on the following: (i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) how to enhance the quality, utility, and clarity of the information to be collected; (iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information:

Title of Collection: State Notification to Consumers of Motor Vehicle Recall Status.

OMB Control Number: None.

Type of Request: New information collection request.

Type of Review: Regular.

Form Number: OMB SF 424, OMB SF 424A, and OMB SF 424B.

Requested Expiration Date of Approval: 3 years from date of approval.

Abstract: NHTSA is responsible for reducing deaths, injuries and economic losses resulting from motor vehicle crashes. This is accomplished by setting and enforcing safety performance standards for motor vehicles and motor vehicle equipment, and through grants to state and local governments to enable them to conduct effective local highway safety programs. NHTSA investigates safety defects in motor vehicles; sets and enforces fuel economy standards; helps states and local communities reduce the threat of impaired drivers; promotes the use of safety belts, child safety seats and air bags; investigates odometer fraud; establishes and enforces vehicle anti-theft regulations; and provides consumer information on motor vehicle safety issues.

The National Traffic and Motor Vehicle Safety Act, 49 U.S.C. 30101, *et. seq.,* as amended (the Safety Act), requires a motor vehicle manufacturer to notify the owners and purchasers of its vehicles of a safety-related defect, or that the vehicle does not comply with an applicable Federal motor vehicle safety standard.[1] A vehicle manufacturer must provide notice of a recall, in a manner prescribed through

[1] 49 U.S.C. 30118.

regulation by NHTSA, to each person registered under State law as the owner and whose name and address are reasonably ascertainable by the manufacturer through State records or other available sources or, if a registered owner is not notified through State registration information, to the most recent purchaser known to the manufacturer.[2]

In order to identify owners of vehicles subject to a safety-related recall and provide notification to them, a motor vehicle manufacturer typically contracts with a third party that obtains vehicle registration data for the affected vehicles from State motor vehicle administrations. The motor vehicle manufacturer then notifies owners and purchasers by U.S. Mail about the safety recall and, among other things, about how to obtain a remedy to fix the defect or noncompliance.[3] To obtain a remedy, the consumer must then present the recalled motor vehicle to an authorized dealer for the dealer to remedy the defect or noncompliance. 49 U.S.C. 30120.

Recall completion rates can and do vary widely depending on a variety of factors such as the age and type of vehicle, as well as owners' perception of relative risk.[4] Considering this wide range, regardless of completion averages, the fact remains that there are at any time tens of millions of vehicles on the road with unremedied safety defects or noncompliances, each one creating a safety risk. NHTSA and the motor vehicle industry have sought to improve notice of safety-related defects to owners and to develop ways to increase the rate at which owners complete the remedy identified in the notice.

In 2016, in accordance with Section 24105 of the Fixing America's Surface Transportation (FAST) Act, Public Law 114–94, NHTSA announced a pilot program to evaluate the feasibility and effectiveness of a State process to inform consumers of open motor vehicle recalls at the time of motor vehicle registration. The grant was conditioned upon a State having the capability to use a vehicle identification number (VIN) to identify whether the specific vehicle was subject to an open safety recall. In 2017, NHTSA awarded the Maryland Motor Vehicle Administration a grant to provide vehicle owners and lessees notice of open safety related recalls on their vehicles. Maryland began notifying vehicle owners and lessees in the Spring of 2018.

Since the start of the Maryland notification program, several States have expressed an interest in partnering with NHTSA to provide similar recall notification to consumers in their states. While the Maryland Pilot Program offers a promising effort to increase consumer awareness to repair open safety recalls (and an opportunity to measure the effectiveness of such notification), additional notification by State DMVs would increase consumer awareness of open safety recalls and increase the repair rate of recalled vehicles. NHTSA believes such efforts will ultimately reduce the risk of a crash or injury due to a safety defect. Under its existing authority provided in the Safety Act, NHTSA is offering this opportunity to further develop this State to consumer notification to increase awareness of open recalls.

NHTSA encourages applicants to be creative and innovative when developing a proposal (application) for this grant. NHTSA is interested in proposals that provide vehicle owners and lessees with frequent notifications at touchpoints between the State and the vehicle. For example, NHTSA is interested in proposals that may offer options at the time of vehicle registration and other unique notification methods (or even follow-up notification). One potential option is to have notification at the time of registration and at motor vehicle emissions and/or safety inspection stations. A State is free to propose a process to make use of the functionality that may exist through its inspection stations or other intersection between the State and the consumer's vehicle. NHTSA does not want to discourage innovative approaches, provided they satisfy the program requirements of notification at the intersection of a vehicle owner or lessee and the State.

NHTSA is also interested in proposals that provide an analysis of recall completion data on an ongoing basis to assist in program evaluation, or assessment of owners' attitudes toward a particular recall notification protocol. In particular, NHTSA is interested in ways for a State to identify the motor vehicles that were remedied following notification of an open recall by the State. NHTSA looks forward to reviewing resourceful approaches that will motivate owners to remedy open recalls.

While this funding opportunity will be made available to all states, NHTSA anticipates an estimated twenty (20) state applications. NHTSA will require these applications not exceed 25 pages (not including resumes or appendices). NHTSA will also require OMB Standard Form (SF) 424 (including 424 ''Application for Federal Assistance,'' 424A ''Budget Information for Non-Construction Programs,'' and 424B ''Assurances for Non-Construction Programs''), with the required information filled in and certified assurances signed. NHTSA estimates the burden for completing these applications at 3,200 hours total (160 hours × 20 state applicants = 3,200 hours) to allow each applicant thirty (30) days to conduct the necessary research, design their program, and complete the application package.

Affected Public: State vehicle registration authorities.

Estimated Number of Respondents: 20.

Frequency: One-time.

Number of Responses: 20.

Estimated Total Annual Burden Hours: 3,200.

Estimated Total Annual Burden Cost: None.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the Department's performance, including whether the information will have practical utility; (b) the accuracy of the Department's estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is most effective if OMB receives it within 30 days of publication.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, *as amended;* and 49 CFR 1:48.

Stephen A. Ridella,

Director, Office of Defects Investigation.

[FR Doc. 2019–15759 Filed 7–24–19; 8:45 am]

BILLING CODE 4910–59–P

[2] 49 U.S.C. 30119(d).

[3] 49 U.S.C. 30119(d) and 49 CFR part 577.

[4] NHTSA, Report to Congress: ''Vehicle Safety Recall Completion Rates Report'' (2018). A copy of the Vehicle Safety Recall Completion Rates Report is located on NHTSA's website at: *https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/18-3122_vehicle_safety_recall_completion_rates_report_to_congress-tag.pdf.*

DEPARTMENT OF THE TREASURY

Renewal of the Charter of the Federal Advisory Committee on Insurance

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of charter renewal.

SUMMARY: The charter for the Federal Advisory Committee on Insurance (FACI) has been renewed for a two-year period beginning June 13, 2019.

FOR FURTHER INFORMATION CONTACT: Lindsey Baldwin, Senior Policy Analyst, Federal Insurance Office, Department of the Treasury, 1500 Pennsylvania Ave. NW, Room 1410 MT, Washington, DC 20220, at (202) 622–3220 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Notice is hereby given under 41 CFR 102–3.65, pursuant to the Federal Advisory Committee Act (5 U.S.C. Appendix), that the FACI has been renewed for an additional two years beginning June 13, 2019. The purpose of the FACI is to present advice and recommendations to the Federal Insurance Office (FIO) in performing its duties and authorities. The advice and recommendations may cover specific or general insurance topics, processes, studies, and/or reports. The duties of the FACI shall be solely advisory and shall extend only to the submission of advice and recommendations, which shall be non-binding, to FIO. The FACI meets on a periodic basis, and its membership is balanced to include a cross-section of representative views of state and non-government persons having an interest in the duties and authorities of FIO.

Dated: July 22, 2019.

Steven Seitz,

Director, Federal Insurance Office.

[FR Doc. 2019–15847 Filed 7–24–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Open Meeting of the Advisory Committee on Risk-Sharing Mechanisms

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of open meeting.

SUMMARY: This notice announces that the U.S. Department of the Treasury's Advisory Committee on Risk-Sharing Mechanisms (''Committee'' or ''ACRSM'') will convene a meeting on Monday, August 12, 2019, in the Cash Room, Room 2121, 1500 Pennsylvania Ave. NW, Washington, DC 20220, from 1:30 p.m.–4:30 p.m. Eastern Time. The meeting is open to the public, and the site is accessible to individuals with disabilities.

DATES: The meeting will be held on Monday, August 12, 2019, from 1:30 p.m.–4:30 p.m. Eastern Time.

ADDRESSES: The Committee meeting will be held in Room 2121 (Cash Room), Department of the Treasury, 1500 Pennsylvania Ave. NW, Washington, DC 20220. The meeting will be open to the public. Because the meeting will be held in a secured facility, members of the public who plan to attend the meeting must either:

1. Register online. Attendees may visit *http://www.cvent.com/d/zyqw21* and fill out a secure online registration form. A valid email address will be required to complete online registration.

(**Note:** Online registration will close at 5:00 p.m. Eastern Time on Monday, August 5, 2019.)

2. Contact the Federal Insurance Office at (202) 622–3220, by 5:00 p.m. Eastern Time on Monday, August 5, 2019, and provide registration information.

Requests for reasonable accommodations under Section 504 of the Rehabilitation Act should be directed to Mariam G. Harvey, Office of Civil Rights and Diversity, Department of the Treasury at (202) 622–0316, or *mariam.harvey@do.treas.gov.*

FOR FURTHER INFORMATION CONTACT: Lindsey Baldwin, Senior Policy Analyst, Federal Insurance Office, Department of the Treasury, 1500 Pennsylvania Ave. NW, Room 1410 MT, Washington, DC 20220, at (202) 622–3220 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided in accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 10(a)(2), through implementing regulations at 41 CFR 102–3.150.

Public Comment: Members of the public wishing to comment on the business of the Advisory Committee on Risk-Sharing Mechanisms are invited to submit written statements by any of the following methods:

Electronic Statements

- Send electronic comments to *acrsm@treasury.gov.*

Paper Statements

- Send paper statements in triplicate to the Advisory Committee on Risk-Sharing Mechanisms, Department of the Treasury, 1500 Pennsylvania Ave. NW, Room 1410 MT, Washington, DC 20220.

In general, the Department of the Treasury will post all statements on its website *https://www.treasury.gov/initiatives/fio/acrsm/Pages/default.aspx* without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department of the Treasury will also make such statements available for public inspection and copying in the Department of the Treasury's Library, 720 Madison Place NW, Room 1020, Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect statements by telephoning (202) 622–2000. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Background: The Committee provides advice and recommendations to the Federal Insurance Office (FIO) with respect to the creation and development of non-governmental, private market risk-sharing mechanisms for protection against losses arising from acts of terrorism.

Tentative Agenda/Topics for Discussion: This will be first Committee meeting of 2019. In this meeting, the ACRSM will address, consistent with its charter's mandate, topics related to the role of nongovernmental mechanisms in supporting the terrorism risk insurance market. In this meeting, the ACRSM will receive an update from FIO, address the use of subcommittees to fulfill the ACRSM's mandate, and identify the ACRSM's priorities for 2019.

Dated: July 19, 2019.

Steven Seitz,

Director, Federal Insurance Office.

[FR Doc. 2019–15848 Filed 7–24–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0018]

Agency Information Collection Activity: Application for Accreditation as Service Organization Representative

AGENCY: Office of General Counsel, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of General Counsel (OGC), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the

agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 23, 2019.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Jonathan Taylor, Office of the General Counsel (022D), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *jonathan.taylor2@va.gov.* Please refer to ''OMB Control No. 2900–0018'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Jonathan Taylor at (202) 461–7699 or FAX (202) 273–6404.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, OGC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of OGC's functions, including whether the information will have practical utility; (2) the accuracy of OGC's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 5901, 5902, 5904; 38 CFR 14.629, 14.633.

Title: Application for Accreditation as Service Organization Representative.

OMB Control Number: 2900–0018.

Type of Review: Reinstatement of a previously approved collection.

Abstract: Service organizations are required to file an application with VA to establish eligibility for accreditation for representatives of that organization to represent benefit claimants before VA. VA Form 21 is completed by service organizations to establish accreditation for representatives and recertify the qualifications of accredited representatives.

Organizations requesting cancellation of a representative's accreditation based on misconduct, incompetence, or resignation to avoid cancellation of accreditation based upon misconduct or incompetence are required to inform VA of the specific reason for the cancellation request. VA will use the information collected to determine whether service organizations' representatives continue to meet regulatory eligibility requirements to ensure claimants have qualified representatives to assist in the preparation, presentation and prosecution of their claims for benefits.

Affected Public: Individuals, not-for-profit institutions, and state, local, or tribal governments.

Estimated Annual Burden: 1,013 hours (650 hours for new applicants, 350 hours for recertifications, and 13 hours for accreditation cancellation information responses).

Estimated Average Burden per Respondent: 13 minutes (15 minutes for new applicants, 10 minutes for recertifications, and 60 minutes for accreditation cancellation information responses).

Frequency of Response: One time.

Estimated Number of Respondents: 4,713 (2,600 new applicants, 2,100 recertifications, and 13 accreditation cancellation information responses).

By direction of the Secretary.

Danny S. Green,

VA Interim Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2019–15782 Filed 7–24–19; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0800]

Agency Information Collection Activity under OMB Review: Airborne Hazards and Open Burn Pit Registry (AHOBPR) Web-Accessible Self-Assessment/ Questionnaire

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Health Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 26, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0800'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 421–1354 or email *danny.green2@va.gov* Please refer to ''OMB Control No. 2900–0800'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Airborne Hazards and Open Burn Pit Registry (AHOBPR) Web-accessible Self-Assessment/ Questionnaire, VA Form 10–10066.

OMB Control Number: 2900–0800.

Type of Review: Reinstatement with change of a previously approved collection.

Abstract: Public Law 112–260 Section 201, enacted by President Obama on 10 January 2013, required Department of Veterans Affairs (VA) to establish and maintain an ''Airborne Hazards and Open Burn Pit Registry (AHOBPR)'' no later than one year from enactment. VA launched the AHOBPR in June 2014. There is no sunset date identified in the law. The Secretary of Veterans Affairs may ''include any information in such registry that the Secretary of Veterans Affairs determines necessary to ascertain and monitor the health effects of the exposure of members of the Armed Forces to toxic airborne chemicals and fumes caused by open burn pits.'' Currently, VA plans to operate the AHOBPR indefinitely, and we request approval to continue administering the questionnaire. The Qarmat Ali (QA) program is a new request for a follow-up information collection for a subset of Veterans impacted by a specific airborne hazard. In the Spring and Summer of 2003,

approximately 700 U.S. Servicemembers may have been impacted by a specific airborne hazard while serving at a water injection plant in Qarmat Ali, Iraq. The Department of Defense (DoD) was unable to determine specific exposure levels near the water treatment facility. In 2010, in response to DoD's notification, the VA offered no-cost medical evaluations and encouraged the cohort to enroll in a new Qarmat Ali medical surveillance program within the Gulf War Registry. The QA cohort is also eligible to participate in the AHOBPR program due to their deployment to Iraq. As part of the planned 5-year periodic medical follow-up and surveillance program, self-reported information will be collected through the AHOBPR as outlined above. Information collected is voluntary and is used to provide outreach and quality health services to AHOBPR participants. Collected data contributes to VA's ability to understand the potential health effects of the exposure to burn pit emissions and other airborne hazards during deployment, such as particulate matter.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 84 FR 19829 on May 6, 2019, pages 19829 and 19830.

Airborne Hazards and Open Burn Pit Registry (AHOBPR) Self-Assessment/ Questionnaire

Affected Public: Individuals and households.

Estimated Annual Burden: 33,333 hours.

Estimated Average Burden per Respondent: 40 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 50,000.

Subset of AHOBPR, Qarmat Ali Questionnaire

Affected Public: Individuals and households.

Estimated Annual Burden: 114 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 686.

By direction of the Secretary.

Danny S. Green,

Interim VA Clearance Officer, Office of Quality, Performance and Risk (OQPR), Department of Veterans Affairs.

[FR Doc. 2019–15785 Filed 7–24–19; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0605]

Agency Information Collection Activity: Application for Accreditation as a Claims Agent or Attorney, Filing of Representatives' Fee Agreements and Motions for Review of Such Fee Agreements

AGENCY: Office of General Counsel, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of General Counsel (OGC), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 23, 2019.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Jonathan Taylor, Office of General Counsel (022D), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *jonathan.taylor2@va.gov*. Please refer to ''OMB Control No. 2900–0605'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Jonathan Taylor at (202) 461–7699 or FAX (202) 273–6404.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, OGC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of OGC's functions, including whether the information will have practical utility; (2) the accuracy of OGC's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 5901, 5904; 38 CFR 14.629, 14.636.

Title: Application for Accreditation as a Claims Agent or Attorney, Filing of Representatives' Fee Agreements and Motions for Review of Such Fee Agreements.

OMB Control Number: 2900–0605.

Type of Review: Reinstatement of a previously approved collection.

Abstract: Applicants seeking accreditation as claims agents or attorneys to represent benefits claimants before VA must complete VA Form 21a. The applicant is required to file the application with OGC to establish initial eligibility for accreditation. The information requested includes basic identifying information, as well as certain information concerning training and experience, military service, and employment. The information is used to evaluate qualifications, ensure against conflicts of interest, and to establish that statutory and regulatory eligibility requirements, *e.g.,* good character and reputation, are met. If a potential area of concern is identified on the application, additional information may be requested. Applicants who become accredited as agents and attorneys may not lawfully represent claimants without completing and maintaining accreditation requirements. The data is used to determine the applicant's eligibility for accreditation as a claims agent or attorney. The information collected with regard to an attorney or agent's good standing with other courts, bars, and Federal and State agencies and completion of their ongoing CLE requirements is used by OGC in monitoring accredited attorneys and agents to determine whether they continue to have the appropriate character and reputation and that they remain fit to prepare, present, and prosecute VA benefit claims.

The data collected under Filing of Representatives' Fee Agreements is used by OGC to associate the fee agreement

with the attorney or agent of record and for potential use in a reasonableness review. The fee agreement information is used by VA's Veterans Benefits Administration (VBA) to associate the fee agreement with the claimant's claims file for potential use in processing as the direct payment of a fee from the claimant's past-due benefits award. The information provided in the fee agreements are used by both VBA and OGC to determine whether they are in compliance with the statutes and regulations governing paid representation. The data collected under Motions for Review of Such Fee Agreements is used when a motion is filed by a claimant or raised sua sponte by VA to determine the reasonableness of an agent or attorney fee from a claimant's award of VA benefits. Also, when a claimant receives an award of benefits and has retained more than one attorney or agent who has been found eligible for direct payment of fees, the data is used to determine each of the attorney's or agent's contribution to and responsibility for the ultimate outcome of the claimant's claim.

Affected Public: Individuals and businesses or other for-profit organizations.

Estimated Annual Burden:

a. *Application for Accreditation as a Claims Agent, VA Form 21a:* 2,137.5 hours (975 hours for initial responses by attorneys, 225 hours for initial responses by non-attorneys, 187.5 hours for follow up responses by non-attorneys, and 750 hours for recertifications by accredited attorneys and agents)

b. *Filing of Representatives' Fee Agreements:* 3,125 hours (750 hours for first time filers and 2,375 hours for repeat filers).

c. *Motions for Review of Such Fee Agreements:* 420 hours.

Estimated Average Burden per Respondent:

a. *Application for Accreditation as a Claims Agent or Attorney, VA Form 21a:* 20 minutes (45 minutes for initial responses by attorneys, 45 minutes for initial responses by non-attorneys, 45 minutes for follow up responses by non-attorneys, and 10 minutes for recertifications by accredited attorneys and agents)

b. *Filing of Representatives' Fee Agreements:* 13 minutes (1 hour for first time filers and 10 minutes for repeat filers).

c. *Motions for Review of Such Fee Agreements:* 2 hours.

Frequency of Response: One time.

Estimated Number of Respondents:

a. *Application for Accreditation as a Claims Agent, VA Form 21a:* 6,350 (1,300 initial responses by attorneys, 300 initial responses by non-attorneys, 250 follow up responses by non-attorneys, and 4,500 recertifications by accredited attorneys and agents).

b. *Filing of Representatives' Fee Agreements:* 15,000 (750 first time filers and 14,250 repeat filers).

c. *Motions for Review of Such Fee Agreements:* 210.

By direction of the Secretary.

Danny S. Green,

VA Interim Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2019–15783 Filed 7–24–19; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board, Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, that the subcommittees of the Rehabilitation Research and Development Service Scientific Merit Review Board will he held Tuesday, August 6 through Friday, August 9, 2019, at the 20 F Conference Center, 20 F Street NW, Washington, DC 20001; and Tuesday, October 29 and Wednesday, October 30, 2019, at the Crowne Plaza Washington National Airport, 1480 Crystal Drive, Arlington, VA 22202. The meetings will begin at 8:00 a.m. and end at 5:00 p.m., on the dates listed below:

Meeting	Date(s)
Chronic Medical Conditions and Aging.	August 6, 2019.
Spinal Cord Injury/Disorders and Neuropathic Pain.	August 6, 2019.
Behavioral Health and Social Reintegration.	August 6–7, 2019.
Career Development Program.	August 6–7, 2019.
Sensory Systems and Communication Disorders.	August 7, 2019.
Regenerative Rehabilitation	August 8, 2019.
Rehabilitation Engineering and Prosthetics/Orthotics.	August 8, 2019.
Brain Health and Injury	August 8–9, 2019.
Musculoskeletal Health and Function.	August 8–9, 2019.
Center and Research Enhancement Award Program.	October 29–30, 2019.

The subcommittee meetings will be open to the public for approximately one-half hour at the start of each meeting to cover administrative matters and to discuss the general status of the program.

The objective of the Board is to provide for the fair and equitable selection of the most meritorious research projects for support by VA research funds and to offer advice for research program officials on program priorities and policies. The ultimate objective of the Board is to ensure that the VA Rehabilitation Research and Development program promotes functional independence and improves the quality of life for impaired and disabled Veterans.

Board members advise the Director, Rehabilitation Research and Development Service and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human and animal subjects of Rehabilitation Research and Development proposals. The Board does not consider grants, contracts, or other forms of extramural research.

Members of the public who wish to attend the open portion of the teleconference sessions may dial 1 (800) 767–1750, participant code 35847. The remaining portion of each subcommittee meeting will be closed to the public for the discussion, examination, reference to, and oral review of the research applications and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. Sec. 552b(c)(6) and (9)(B).

No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to attend (by phone or in person) the open portion of a subcommittee meeting must contact Tiffany Asqueri, Designated Federal Officer, Rehabilitation Research and Development Service, at Department of Veterans Affairs (10X2R), 810 Vermont Avenue NW, Washington, DC 20420, or email *Tiffany.Asqueri@va.gov,* at least five days before the meeting. For further information, please call Mrs. Asqueri at (202) 443–5757.

Dated: July 19, 2019.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–15779 Filed 7–24–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Homeless Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Advisory Committee on Homeless Veterans will be held August 28–29, 2019 from 8:00 a.m. to 5:00 p.m. (Central Standard Time). The meeting sessions will take place at Minnesota Housing, 400 Wabasha Street North, Suite 400, Lake Superior Conference Room, Saint Paul, Minnesota 55102. Sessions are open to the public, except when the Committee is conducting tours of VA and other Veteran service facilities, participating in off-site events, and participating in administrative workgroup sessions to discuss topics for its recommendations to the Secretary of Veterans Affairs. Tours of VA and Veteran service facilities are closed, to protect Veterans' privacy and personal information in accordance with 5 U.S.C. 552b(c)(6).

The purpose of the Committee is to provide the Secretary of Veterans Affairs with an on-going assessment of the effectiveness of the policies, organizational structures, and services of VA in assisting Veterans at-risk and experiencing homelessness. The Committee shall assemble, and review information related to the needs of homeless Veterans and provide advice on the most appropriate means of providing assistance to that subset of the Veteran population. The Committee will make recommendations to the Secretary of Veterans Affairs regarding such activities.

On Wednesday, August 28, 2019, the Committee will convene an open session and the agenda will include briefings from officials at VA and other federal, state and local agencies regarding services for homeless Veterans. On Thursday, August 29, 2019, the Committee will convene a closed session to conduct tours of VA and Veteran service facilities, participating in off-site events, and participating in administrative workgroup sessions to discuss topics for its recommendations to the Secretary of Veterans Affairs. Tours of VA and Veteran service facilities are closed, to protect Veterans' privacy and personal information, in accordance with 5 U.S.C. 552b(c)(6).

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments on issues affecting homeless Veterans for review by the Committee to Mr. Anthony Love, Designated Federal Officer, Veterans Health Administration, Homeless Programs Office (10NC1), Department of Veterans Affairs, 811 Vermont Avenue NW (10NC1), Washington, DC 20420, or via email at *Anthony.Love@va.gov* and *Leisa.Davis@va.gov.*

Members of the public who wish to attend should contact *Anthony.Love@va.gov* and *Leisa.Davis@va.gov* of the Veterans Health Administration, Homeless Programs Office no later than August 1, 2019, to provide their name, professional affiliation, email address, and phone number. There will also be a call-in number at 1–800–767–1750; access code: 50653#. Attendees who require reasonable accommodations should also state so in their requests. Please arrive to Minnesota Housing, 400 Wabasha Street North, Suite 400, Lake Superior Conference Room, Saint Paul, Minnesota 55102, at least 20 (twenty) minutes before the meeting start time to clear the building security checkpoint.

Dated: July 22, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–15799 Filed 7–24–19; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

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No. 143 July 25, 2019

Part II

Social Security Administration

20 CFR Part 404

Revised Medical Criteria for Evaluating Digestive Disorders and Skin Disorders; Proposed Rule

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2017–0042]

RIN 0960–AG65

Revised Medical Criteria for Evaluating Digestive Disorders and Skin Disorders

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving digestive and skin disorders in adults and children under titles II and XVI of the Social Security Act (Act). The proposed revisions reflect our adjudicative experience, advances in medical knowledge, and comments we received from experts and the public in response to two advance notices of proposed rulemaking (ANPRM).

DATES: To ensure that your comments are considered, we must receive them by no later than September 23, 2019.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2017–0042, so that we may associate your comments with the correct regulation.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the *Search* function to find docket number SSA–2017–0042. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1020. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Why are we proposing to revise the listings for digestive and skin disorders?

We last published final rules that revised the digestive disorders listings on October 19, 2007, and the skin disorders listings on June 9, 2004.[1] We are proposing these revisions to reflect our adjudicative experience, advances in medical knowledge, and comments we received from experts and the public in response to two ANPRMs.

How did we develop these proposed rules?

In developing these proposed rules:

- We published an ANPRM for digestive disorders in the **Federal Register** on December 12, 2007.[2] We invited the public to comment on whether we should add a digestive disorders listing based on functional limitations and, if so, what criteria we should use. We received 12 comments. Ten commenters recommended adding a digestive disorders listing with functional criteria and suggested we use the same functional criteria we use in other body systems.
- We published an ANPRM for skin disorders in the **Federal Register** on November 10, 2009.[3] We invited the public to send us written comments and suggestions about whether and how we should revise the skin disorders listings. We received three comments.

The comments we received from these two ANPRMs informed the proposed changes in this NPRM. In developing these proposed rules, we also considered information from several other sources, including:

- Medical experts in gastroenterology and dermatology;
- Advocacy groups for people with digestive and skin disorders;
- People with digestive and skin disorders and their families;
- People who make and review disability determinations and decisions for us in State agencies, in our Office of Hearings Operations, and in our Office of Analytics, Review, and Oversight; and
- The published sources we list in the References section at the end of this preamble.

How is this NPRM organized?

Digestive Disorders Overview of Proposed Revisions

- Adult digestive disorders proposed revisions
- Child digestive disorders proposed revisions

The following chart shows the heading of the current and proposed sections of the adult introductory text and listings for digestive disorders:

Current sections of the adult introductory text and listings for the digestive system	Proposed sections of the adult introductory text and listings for digestive disorders
Introductory Text, 5.00	
A. What kinds of disorders do we consider in the digestive system?	A. Which digestive disorders do we evaluate in this body system?
B. What documentation do we need?	B. What evidence do we need to evaluate your digestive disorder? [5.00 H.]
C. How do we consider the effects of treatment?	
D. How do we evaluate chronic liver disease?	C. What is chronic liver disease (CLD), and how do we evaluate it under 5.05?
E. How do we evaluate inflammatory bowel disease (IBD)?	D. What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?
F. How do we evaluate short bowel syndrome (SBS)?	E. What is short bowel syndrome (SBS), and how do we evaluate it under 5.07?

[1] See 72 FR 59398 (2007) and 69 FR 32260 (2004).

[2] See 72 FR 70527.

[3] See 74 FR 57972, with the docket number corrected at 74 FR 62518.

Current sections of the adult introductory text and listings for the digestive system	Proposed sections of the adult introductory text and listings for digestive disorders
G. How do we evaluate weight loss due to any digestive disorder?	F. How do we evaluate malnutrition due to any digestive disorder under 5.08?
[5.00 D.12.]	G. How do we evaluate digestive organ transplantation?
H. What do we mean by the phrase "consider under a disability for 1 year"?	[5.00 C.2. and G.]
[5.00 C.6.]	H. How do we evaluate your digestive disorder if there is no record of ongoing treatment?
	I. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?
I. How do we evaluate impairments that do not meet one of the digestive disorder listings?	J. How do we evaluate digestive disorders that do not meet one of these listings?
Listings	
5.01 Category of Impairments, Digestive System	5.01 Category of Impairments, Digestive Disorders
5.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion.	5.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions
5.03 [Reserved]	5.03 [Reserved]
5.04 [Reserved]	5.04 [Reserved]
5.05 Chronic liver disease (CLD)	5.05 Chronic liver disease (CLD)
5.06 Inflammatory bowel disease (IBD)	5.06 Inflammatory bowel disease (IBD)
5.07 Short bowel syndrome (SBS)	5.07 Short bowel syndrome (SBS)
5.08 Weight loss due to any digestive disorder	5.08 Malnutrition due to any digestive disorder
5.09 Liver transplantation	5.09 Liver transplantation
	5.10 [Reserved]
	5.11 Small intestine transplantation
	5.12 Pancreas transplantation

The following chart shows the heading of the current and proposed sections of the child introductory text and listings for digestive disorders:

Current sections of the child introductory text and listings for the digestive system	Proposed sections of the child introductory text and listings for digestive disorders
Introductory Text, 105.00	
A. What kinds of disorders do we consider in the digestive system?	A. Which digestive disorders do we evaluate in this body system?
B. What documentation do we need?	B. What evidence do we need to evaluate your digestive disorder?
C. How do we consider the effects of treatment?	[105.00 J.]
D. How do we evaluate chronic liver disease?	C. What is chronic liver disease (CLD), and how do we evaluate it under 105.05?
E. How do we evaluate inflammatory bowel disease (IBD)?	D. What is inflammatory bowel disease (IBD), and how do we evaluate it under 105.06?
F. How do we evaluate short bowel syndrome (SBS)?	E. What is short bowel syndrome (SBS), and how do we evaluate it under 105.07?
G. How do we evaluate growth failure due to any digestive disorder? ...	F. How do we evaluate growth failure due to any digestive disorder under 105.08?
[105.00 D.13.]	G. How do we evaluate digestive organ transplantation?
H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?	H. How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?
I. How do we evaluate esophageal stricture or stenosis?	I. How do we evaluate esophageal stricture or stenosis?
J. What do we mean by the phrase "consider under a disability for 1 year"?	[105.00 C.2., C.4., and G.]
[105.00 C.6.]	J. How do we evaluate your digestive disorder if there is no record of ongoing treatment?
	K. How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?
K. How do we evaluate impairments that do not meet one of the digestive disorder listings?	L. How do we evaluate digestive disorders that do not meet one of these listings?
Listings	
105.01 Category of Impairments, Digestive System	105.01 Category of Impairments, Digestive Disorders
105.02 Gastrointestinal hemorrhaging from any cause, requiring blood transfusion.	105.02 Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions
105.03 [Reserved]	105.03 [Reserved]
105.04 [Reserved]	105.04 [Reserved]
105.05 Chronic liver disease	105.05 Chronic liver disease (CLD)
105.06 Inflammatory bowel disease (IBD)	105.06 Inflammatory bowel disease (IBD)
105.07 Short bowel syndrome (SBS)	105.07 Short bowel syndrome (SBS)
105.08 Growth failure due to any digestive disorder	105.08 Growth failure due to any digestive disorder

Current sections of the child introductory text and listings for the digestive system	Proposed sections of the child introductory text and listings for digestive disorders
105.09 Liver transplantation	105.09 Liver transplantation
105.10 Need for supplemental daily enteral feeding via a gastrostomy	105.10 Need for supplemental daily enteral feeding via a gastrostomy
	105.11 Small intestine transplantation
	105.12 Pancreas transplantation

Skin Disorders Overview of Proposed Revisions

- Adult skin disorders proposed revisions
- Child skin disorders proposed revisions

The following chart shows the heading of the current and proposed sections of the adult introductory text and listings for skin disorders:

Current sections of the adult introductory text and listings for the skin disorders	Proposed sections of the adult introductory text and listings for skin disorders
Introductory Text, 8.00	
A. What skin disorders do we evaluate with these listings?	A. Which skin disorders do we evaluate under these listings?
B. What documentation do we need?	B. What are our definitions for the following terms used in this body system?
C. How do we assess the severity of your skin disorder(s)?	C. What evidence do we need to evaluate your skin disorder?
D. How do we assess impairments that may affect the skin and other body systems?	D. How do we evaluate the severity of skin disorders?
E. How do we evaluate genetic photosensitivity disorders?	E. How do we evaluate genetic photosensitivity disorders under 8.07?
F. How do we evaluate burns?	F. How do we evaluate burns under 8.08?
G. How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?	G. How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?
H. How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?	H. How do we evaluate disorders in other body systems that affect the skin?
I.	I. How do we evaluate skin disorders that do not meet one of these listings?
Listings	
8.01 Category of Impairments, Skin Disorders	8.01 Category of Impairments, Skin Disorders
8.02 Ichthyosis	8.02 [Reserved]
8.03 Bullous disease	8.03 [Reserved]
8.04 Chronic infections of the skin or mucous membranes	8.04 [Reserved]
8.05 Dermatitis	8.05 [Reserved]
8.06 Hidradenitis suppurativa	8.06 [Reserved]
8.07 Genetic photosensitivity disorders	8.07 Genetic photosensitivity disorders
8.08 Burns	8.08 Burns
	8.09 Chronic conditions of the skin or mucous membranes

The following chart shows the heading of the current and proposed sections of the child introductory text and listings for skin disorders:

Current sections of the child introductory text and listings for the skin disorders	Proposed sections of the child introductory text and listings for skin disorders
Introductory Text, 108.00	
A. What skin disorders do we evaluate with these listings?	A. Which skin disorders do we evaluate under these listings?
B. What documentation do we need?	B. What are our definitions for the following terms used in this body system?
C. How do we assess the severity of your skin disorder(s)?	C. What evidence do we need to evaluate your skin disorder?
D. How do we assess impairments that may affect the skin and other body systems?	D. How do we evaluate the severity of skin disorders?
E. How do we evaluate genetic photosensitivity disorders?	E. How do we evaluate genetic photosensitivity disorders under 108.07?
F. How do we evaluate burns?	F. How do we evaluate burns under 108.08?
G. How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?	G. How do we evaluate chronic conditions of the skin or mucous membranes under 108.09?
H. How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?	H. How do we evaluate disorders in other body systems that affect the skin?
I.	I. How do we evaluate skin disorders that do not meet one of these listings?
Listings	
108.01 Category of Impairments, Skin Disorders	108.01 Category of Impairments, Skin Disorders

Current sections of the child introductory text and listings for the skin disorders	Proposed sections of the child introductory text and listings for skin disorders
108.02 Ichthyosis	108.02 [Reserved]
108.03 Bullous disease	108.03 [Reserved]
108.04 Chronic infections of the skin or mucous membranes	108.04 [Reserved]
108.05 Dermatitis	108.05 [Reserved]
108.06 Hidradenitis suppurativa	108.06 [Reserved]
108.07 Genetic photosensitivity disorders	108.07 Genetic photosensitivity disorders
108.08 Burns	108.08 Burns
	108.09 Chronic conditions of the skin or mucous membranes

What revisions are we proposing for digestive disorders?

We propose to:

- Change the name of the body system from ''Digestive System'' to ''Digestive Disorders'' to be consistent with the nomenclature of all body systems;
- Revise and reorganize the introductory text to provide guidance for using the revised criteria in listings;
- Revise the SSA Chronic Liver Disease (SSA CLD) score in listings 5.05 and 105.05;
- Add criteria to listings 5.06 and 105.06 for repeated complications of IBD;
- Add adult and child listings for small intestine transplantation (proposed 5.11 and 105.11) and pancreas transplantation (proposed 5.12 and 105.12); and
- Make minor editorial revisions to the introductory text and listings for clarity.

Proposed 5.00—Introductory Text to the Adult Digestive Disorders Listings

The following describes changes we are proposing to the introductory text.

Proposed 5.00C—What is chronic liver disease (CLD), and how do we evaluate it under 5.05?

We propose to:

- Redesignate current 5.00C (*How do we consider the effects of treatment?*) as proposed 5.00H and remove some of the guidance in current 5.00C (*paragraphs 1 through C4*) because the guidance is a restatement of general policy on how we consider the effects of treatment that is not unique to digestive disorders but applicable to all medically determinable impairments;
- Redesignate current 5.00D (*How do we evaluate chronic liver disease?*) as proposed 5.00C;
- Remove the discussion of hepatitis B and C in current 5.00D4 (*Chronic viral hepatitis infections*) because it does not contain guidance on evaluating CLD and continue to evaluate CLD resulting from hepatitis B and C under proposed listing 5.05;
- In 5.00C2, incorporate the information about CLD manifestations that is in current 5.00D3 (*Manifestations of chronic liver disease*) and 5.00D5 through 5.00D10 (*Gastrointestinal hemorrhage, Ascites or hydrothorax, Spontaneous bacterial peritonitis, Hepatorenal syndrome, Hepatopulmonary syndrome,* and *Hepatic encephalopathy),* provide guidance on how to assess the severity of these manifestations, and include the guidance in current 5.00H (*What do we mean by the phrase ''consider under a disability for 1 year''?*); and
- In 5.00C3, incorporate the information about the SSA CLD score calculation in current 5.00D11 (*End stage liver disease (ESLD) documented by scores from the SSA Chronic Liver Disease (SSA CLD) calculation*) and add an SSA CLD calculation example.

Proposed 5.00D—What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?

We propose to redesignate current 5.00E (*How do we evaluate inflammatory bowel disease?*) as proposed 5.00D. We would describe the factors we consider when we evaluate impaired functioning due to IBD under proposed 5.06C. We would also define ''marked'' limitation and explain the three areas of functioning we use in the proposed listing.

Proposed 5.00E—What is short bowel syndrome (SBS), and how do we evaluate it under 5.07?

We propose to redesignate current 5.00F (*How do we evaluate short bowel syndrome?*) as proposed 5.00E. We would also remove text about long-term complications of SBS because this content, while not incorrect, is not necessary to understand in order to evaluate SBS under 5.07.

Proposed 5.00F—How do we evaluate malnutrition due to any digestive disorder under 5.08?

We propose to redesignate current 5.00G (*How do we evaluate weight loss due to any digestive disorder?*) as proposed 5.00F. We would also use the term ''malnutrition'' instead of ''weight loss,'' and clarify that weight loss must be the result of malnutrition caused by a digestive disorder.

Proposed 5.00G—How do we evaluate digestive organ transplantation?

We propose to incorporate the guidance in current 5.00D12 (*Liver transplantation*), and the guidance in 5.00H (*What do we mean by the phrase ''consider under a disability for 1 year''?*), in proposed 5.00G.

Proposed 5.00H—How do we evaluate your digestive disorder if there is no record of ongoing treatment?

In proposed 5.00H, we incorporate the guidance in current 5.00C6, which explains what we do when there is no record of ongoing treatment. As we explained earlier, we removed the guidance in current 5.00C (paragraphs 1 through 4) because this the guidance is a restatement of general policy on how we consider the effects of treatment that is not unique to digestive disorders but applicable to all medically determinable impairments.

Proposed 5.00I—How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?

In proposed 5.00I, we incorporate by reference our regulations for determining whether drug addiction or alcoholism is a contributing factor material to the determination of disability because use of drugs or alcohol may result in a chronic digestive disorder, such as drug-induced hepatitis or alcoholic liver disease.

Proposed 5.00J—How do we evaluate digestive disorders that do not meet one of these listings?

We propose to redesignate current 5.00I (*How do we evaluate impairments that do not meet one of the digestive disorder listings?*) as proposed 5.00J.

Proposed Changes to the Adult Digestive Disorders Listings

Proposed Listing 5.02—Gastrointestinal Hemorrhaging From Any Cause

We propose to change the period during which the criteria in listing 5.02

must occur from a ''6-month period'' to a ''12-month period'' to be consistent with the timeframe criteria in all other body systems within the listings.

Proposed Listing 5.05—Chronic Liver Disease (CLD)

In 5.05A, we propose to clarify the requirement for documenting hemodynamic instability by moving the list of signs of hemodynamic instability from current 5.00D5 (*Gastrointestinal hemorrhage*) to proposed 5.05A. In 5.05B (*Ascites or hydrothorax*), we propose to change the period during which ascites or hydrothorax must occur from a ''6-month period'' to a ''12-month period'' to be consistent with the timeframe criteria in all other body systems within the listings.

In 5.05E1 (*Hepatopulmonary syndrome documented by arterial* P_aO_2), we propose to add ''measured by an ABG test, while at rest, breathing room air, less than or equal to'' to clarify our requirements for a P_aO_2 measurement. In 5.05G (*SSA CLD scores*), we propose to change the SSA CLD score requirement from ''22 or greater'' to ''at least 20.'' A score of at least 20 accurately identifies advanced, end stage liver disease that will prevent a person from engaging in any gainful activity or will lead to death.[4] [5] [6] [7] We also propose to remove the term ''end stage liver disease'' because the evidence we require in order for us to consider chronic liver disease under 5.05G does not need to include the term ''end stage liver disease'' (which may also be referred to as ''chronic liver failure'').

Proposed Listing 5.06—Inflammatory Bowel Disease (IBD)

We propose to remove the low hemoglobin, low serum albumin, and weight loss criteria, which indicate malnutrition, in current 5.06 because we will evaluate those criteria under proposed 5.08 (*Malnutrition due to any digestive disorder*). In 5.06A (*Obstruction of stenotic areas*) and 5.06B (*Combination of clinical findings*), we propose to change the period during which the listing criteria must occur from a ''6-month period'' to a ''12-month period'' to be consistent with the timeframe criteria in all other body systems within the listings.

We also propose to add a criterion (proposed 5.06C) for repeated complications of IBD that result in marked limitation in at least one area of functioning. These criteria characterize complications of IBD that prevent a person from engaging in any gainful activity.[8] [9] [10] [11] This proposed listing combines medical criteria with specific limitations in functioning to identify IBD of listing-level severity. The addition of functional criteria is also consistent with the listings that already include these same functional criteria, which are 7.18 (*Repeated complications of hematological disorders),* 14.02B (*Repeated manifestations of systemic lupus erythematosus*), 14.04D (*Repeated manifestations of systemic sclerosis*), 14.05E (*Repeated manifestations of polymyositis or dermatomyositis*), 14.06B (*Repeated manifestations of undifferentiated or mixed connective tissue disease*), 14.07C (*Repeated manifestations of an immune deficiency disorder*), 14.09D (*Repeated manifestations of inflammatory arthritis*), 14.10B (Sjögren's syndrome), and 14.11I (*Repeated manifestations of HIV infection*).

Proposed Listing 5.07—Short Bowel Syndrome (SBS)

We propose to require ''surgical resection of any amount of the small intestine'' instead of ''surgical resection of more than one-half of the small intestine'' because measurement of the total length of remaining intestine within the abdominal cavity is rarely obtained during surgery.[12] [13] [14]

Proposed Listing 5.08—Malnutrition Due to Any Digestive Disorder

We propose to revise the heading of current 5.08 from ''Weight loss due to any digestive disorder'' to ''Malnutrition due to any digestive disorder,'' and revise the body mass index (BMI) measurement from ''less than 17.5'' to ''less than 18.0.'' We also propose to include the criteria for low hemoglobin, low serum albumin, and the need for supplemental daily enteral or parenteral nutrition, which are in current 5.06B. These criteria are findings indicative of malnutrition, which may result from any digestive disorder, not just IBD. The combination of low BMI measurements and one of these other findings improves the specificity of listing 5.08.[15] Lastly, we propose to change the period during which the listing criteria must occur from a ''6-month period'' to a ''12-month period'' to be consistent with the timeframe criteria in all other body systems within the listings.

Proposed Digestive Organ Transplantation Listings

We propose to add listing 5.11 for small intestine transplantation and listing 5.12 for pancreas transplantation.[16] [17] We currently evaluate small intestine and pancreas transplantations under listing 5.09 for liver transplantation using our medical equivalence rules. The separate listings would allow us to differentiate which digestive organ has been transplanted and allow us to propose future updates to each separate listing, as needed, based on medical advances in the specific organ transplant category.

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Proposed 105.00—Introductory Text to the Child Digestive Disorders Listings

We repeat much of the introductory text of proposed 5.00 in the introductory text of proposed 105.00. This repetition is because the same basic rules apply for evaluating digestive disorders in adults and in children.

Proposed Changes to the Child Digestive Disorders Listings

We are proposing changes in the child listings to correspond with the changes we are proposing in the adult listings. The reasons we gave earlier for changing or removing current criteria for adults also apply to the criteria for children. Additionally, the numbering of the child listings would conform to the adult listings.

What revisions are we proposing for skin disorders?

We propose to:

- Revise and reorganize the introductory text to provide guidance for using the revised criteria in listings;
- Remove and reserve current adult listings 8.02 (*Ichthyosis*), 8.03 (*Bullous disease*), 8.04 (*Chronic infections of the skin or mucous membranes*), 8.05 (*Dermatitis*), and 8.06 (*Hidradenitis suppurativa*) and consolidate the current criteria into one listing for chronic conditions of the skin or mucous membranes (proposed 8.09), and remove and reserve current child listings 108.02 (*Ichthyosis*), 108.03 (*Bullous disease*), 108.04 (*Chronic infections of the skin or mucous membranes*), 108.05 (*Dermatitis*), and 108.06 (*Hidradenitis suppurativa*) and consolidate the current criteria into one listing for chronic conditions of the skin or mucous membranes (proposed 108.09), to strengthen adjudicative ease and more efficiently capture adults and children with skin disorders of listing-level severity;
- Include limitations of physical functioning we use to assess impairment severity, which are explained in current 8.00C and 108.00C (*How do we assess the severity of your skin disorder(s)?*), in the listing criteria for adult listings 8.07B (Other genetic photosensitivity disorders), 8.08 (Burns), and 8.09 (Chronic conditions of the skin or mucous membranes) and child listings 108.07B (Other genetic photosensitivity disorders), 108.08 (Burns), and 108.09 (Chronic conditions of the skin or mucous membranes); and
- Make minor editorial revisions to the introductory text and listings for clarity.

Proposed 8.00—Introductory Text to the Adult Skin Disorders Listings

Most of the guidance in the proposed introductory text is substantively the same as the guidance in the current introductory text. The following is a detailed description of the significant changes we are proposing to the introductory text. In addition to the changes we describe below, we are proposing other, minor changes to the introductory text to clarify how we use the proposed listings to evaluate skin disorders.

Proposed 8.00B—What are our definitions for the following terms used in this body system?

In this new section, 8.00B, we provide definitions for terms, such as ''chronic skin lesions'' and ''contractures,'' that we use in the listings to evaluate skin disorders.

Proposed 8.00C—What evidence do we need to evaluate your skin disorder?

In 8.00C, we incorporate the guidance in current 8.00B (*What documentation do we need?*).

Proposed 8.00D—How do we evaluate the severity of skin disorders?

In 8.00D, we discuss how we evaluate the severity of skin disorders (which is now contained in current 8.00C) and add a clearer explanation for how we quantify limitations in functioning under these listings. In 8.00D1, we explain how we evaluate the severity of skin disorders based on the site(s) of the lesions or contractures and the response to treatment. In 8.00D2, we explain the functional criteria we use to evaluate skin disorders under proposed 8.07B (Other genetic photosensitivity disorders), 8.08 (Burns), and 8.09 (Chronic conditions of the skin or mucous membranes). Chronic skin lesions or contractures may restrict movement and result in limitation(s) of physical functioning (ability to use the upper extremities, stand up from a seated position, or maintain an upright position while standing or walking). In 8.00D3, we propose to replace the term ''flare-ups'' with ''exacerbations.''

In 8.00D4, we propose to incorporate the guidance on symptoms in current 8.00C3 (*Symptoms (including pain)*). In 8.00D5, we propose to incorporate and revise the guidance on treatment in current 8.00D4 (*Disfigurement or deformity*) and 8.00G (*How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?*). We propose to replace the term ''continuing treatment as prescribed'' with ''adherence to prescribed medical treatment'' to be consistent with current medical terminology. In 8.00D5b, we provide guidance on how to evaluate skin disorders after adherence to prescribed medical treatment for 3 months.

In 8.00D5c, we provide guidance on how to evaluate claims in which the prescribed medical treatment is psoralen and ultraviolet A light (PUVA) or biologics. PUVA is a treatment involving exposure to UVA light after taking a biologic medication called psoralen that increases the skin's sensitivity to ultraviolet light. PUVA is generally used under medical supervision when other conservative treatments for skin disorders have proven to be ineffective.[18] [19] [20] [21] We explain that, if a person receives PUVA or biologics, we will defer adjudication until 6 months from the start of treatment unless we can make a fully favorable determination or decision on another basis. In 8.00D6, we clarify how we evaluate cases in which there is no longitudinal record of ongoing treatment.

Proposed 8.00E—How do we evaluate genetic photosensitivity disorders under 8.07?

In 8.00E3, we explain that we will not purchase genetic testing, but will consider the results of this testing if it is in a person's case record. In 8.00E4, we include what the phrase ''inability to function outside of a highly protective environment'' means, which is in current 8.00E2 (*Other genetic photosensitivity disorders*).

Proposed 8.00F—How do we evaluate burns under 8.08?

In 8.00F, we include guidance for evaluating third-degree burns resulting in contractures that have been documented by an acceptable medical source to have reached maximum therapeutic benefit.

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Proposed 8.00G—How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?

In 8.00G, we provide examples of the skin disorders we evaluate under new listing 8.09, which include ichthyosis, bullous diseases, chronic skin infections, dermatitis, and hidradenitis suppurativa.

Proposed 8.00H—How do we evaluate disorders in other body systems that affect the skin?

In 8.00H, we include the guidance in current 8.00D (*How do we assess impairments that may affect the skin and other body systems?*). We also propose to include a new paragraph (8.00H1) on evaluating skin disorders that are complications of diabetes mellitus.

Proposed 8.00I—How do we evaluate skin disorders that do not meet one of these listings?

In 8.00I, we include the guidance in current 8.00H (*How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?*).

Proposed Changes to the Adult Skin Disorders Listings

Proposed Listing 8.07—Genetic Photosensitivity Disorders

We propose to include the functional criteria, which we explain above, directly in 8.07B to evaluate limitation of physical functioning due to a genetic photosensitivity disorder. In some cases, this requirement may be overlooked by adjudicators because the functional criteria are not currently included as listing criteria, but rather are explained in the introductory text.

Proposed Listing 8.08—Burns

We propose to include the functional criteria, which we explain above, directly in 8.08 to evaluate limitation of physical functioning due to burns. In some cases, this requirement may be overlooked by adjudicators because the functional criteria are not currently included as listing criteria, but rather are explained in the introductory text.

Proposed Listing 8.09—Chronic Conditions of the Skin or Mucous Membranes

We propose to remove and reserve current listings 8.02 (*Ichthyosis*), 8.03 (*Bullous disease*), 8.04 (*Chronic infections of the skin or mucous membranes*), 8.05 (*Dermatitis*), and 8.06 (*Hidradenitis suppurativa*) and add listing 8.09 to evaluate these skin disorders. The criteria in the current listings are identical for each type of skin disorder, and all of the named disorders are chronic conditions of the skin or mucous membranes. In proposed 8.09, we propose to include the functional criteria, which we explain above, to evaluate limitation in physical functioning due to these skin disorders. In some cases, this requirement may be overlooked by adjudicators because the functional criteria are not currently included as listing criteria, but rather are explained in the introductory text.

Proposed 108.00—Introductory Text to the Child Skin Disorders Listings

We repeat much of the introductory text of proposed 8.00 in the introductory text of proposed 108.00. This repetition is because the same basic rules apply for evaluating skin disorders in adults also apply to skin disorders in children with one exception—how we evaluate limitation of physical functioning. Children's physical abilities change as they grow and mature. For example, young infants are not able to walk, but do move their extremities and may use them to roll over, crawl, or perform other functions as they develop. To evaluate the severity of skin disorders in children, we propose to use criteria based on a child's ability to independently initiate, sustain, and complete age-appropriate activities.

Proposed Changes to the Child Skin Disorders Listings

We are proposing changes in the child listings to correspond with the changes we are proposing in the adult listings. Other changes are specific to how we evaluate skin disorders in children. The reasons we gave earlier for changing or removing current criteria for adults also apply to the criteria for children. Additionally, the numbering of the child listings would conform to that of the adult listings.

Other Questions

We are interested in receiving public comments on the following topics:

- Are there any digestive or skin disorders that meet one of the proposed listings, but are generally expected to medically improve after a certain amount of time to the point at which the disorders are no longer of listing-level severity? If you believe there are digestive or skin disorders that fit into this category, please tell us by submitting your comments and any supporting research or data on that issue.
- Do the proposed rules for evaluating chronic conditions of the skin or mucous membranes (conditions such as psoriasis and hidradenitis suppurativa) appropriately consider whether treatment regimens interfere with the ability to do any work? If you believe the criteria should be revised, please tell us by submitting your comments and any supporting research or data.
- Should any of the proposed listings for either digestive disorders or skin disorders be combined into one listing or divided into multiple listings to strengthen adjudicative ease and capture adults or children with impairments that are of listing-level severity?
- Based on advances in medical functional restorative treatment of many skin disorders, is our proposal for the durations of persistent treatment appropriate for listing-level severity? Specifically, the current listings for chronic skin infections require that claimants be considered for listing-level severity if exacerbations persist despite adherence to prescribed medical treatment for three months, unless we can make a fully favorable determination or decision on another basis. We propose that, for claimants who have access to treatment with PUVA or biologics, the skin disorder be considered for listing-level severity if exacerbations persist despite treatment for six months from the start of PUVA or biologics. Alternatively, for burns, we propose that, for consideration of listing-level severity, an acceptable medical source document maximum therapeutic benefit and, therefore, a claimant is no longer receiving surgical management. Do these criteria create incentive to not seek medical treatment in order to obtain or maintain access to disability benefits? If you believe the criteria for skin disorder treatment duration should be revised, please tell us by submitting your comments and any supporting research or data.

What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them.[22]

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

[22] Sections 205(a), 702(a)(5), and 1631(d)(1).

Rulemaking Analyses and Notices

We will consider all comments we receive on or before the close of business on the comment closing date indicated above. The comments will be available for examination in the rulemaking docket for these rules at the above address. We will file comments received after the comment closing date in the docket and will consider those comments to the extent practicable. However, we will not respond specifically to untimely comments. We may publish a final rule at any time after close of the comment period.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter, sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand; *e.g.,* grouping and order of sections, use of headings, paragraphing?

When will we start to use these rules?

We will not use these proposed rules until we evaluate public comments and publish final rules in the **Federal Register**. All final rules we issue include an effective date. We will continue to use our current rules until that date. If we publish final rules, we will include a summary of the relevant comments we received and an explanation of how we will apply the new rules.

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed them.

We also determined that these proposed rules meet the plain language requirement of Executive Order 12866.

Executive Order 13132 (Federalism)

We analyzed these proposed rules in accordance with the principles and criteria established by Executive Order 13132, and determined that these proposed rules will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that these proposed rules will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Executive Order 13771

Anticipated Accounting Costs of These Proposed Rules

Anticipated Costs to Our Programs

Our Office of the Chief Actuary estimates, based on the best available data, that this proposed rule, assuming it is finalized and implemented for all disability decisions completed after February 1, 2020, would result in a reduction of $155 million in OASDI benefit payments and a reduction of $55 million in Federal SSI payments over the 10-year period of FY 2019–2028.

Anticipated Administrative Costs to the Social Security Administration

The Office of Budget, Finance, and Management estimated administrative savings of less than 15 work years and $2 million annually, which we consider to be a non-significant amount.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require OMB approval under the Paperwork Reduction Act.

References

We consulted the following references when we developed these proposed rules:

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We will make these references available to you for inspection if you are interested in reading them. Please make arrangements with the contact person shown in this preamble if you would like to review any reference materials.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, survivors, and disability insurance, Reporting and recordkeeping requirements, Social Security.

Andrew Saul,

Commissioner of Social Security.

For the reasons set forth in the preamble, we propose to amend subpart P of part 404 of title 20 of the Code of Federal Regulations as set forth below:

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

Subpart P—Determining Disability and Blindness

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

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 as follows:
■ a. Revise items 6 and 9 of the introductory text before part A;
■ b. In part A, revise the body system name for section 5.00 in the table of contents and sections 5.00 and 8.00; and
■ c. In part B, revise the body system name for section 105.00 in the table of contents and sections 105.00 and 108.00.

The revisions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

6. Digestive Disorders (5.00 and 105.00) [date 5 years from the effective date of the final rule].

* * * * *

9. Skin Disorders (8.00 and 108.00) [date 5 years from the effective date of the final rule].

* * * * *

Part A

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5.00 Digestive Disorders

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5.00 Digestive Disorders

A. *Which digestive disorders do we evaluate in this body system?* We evaluate digestive disorders that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract (the large, muscular tube that extends from the mouth to the anus, where the movement of muscles, along with the release of hormones and enzymes, allows for the digestion of food) in this body system. Examples of such disorders and the listings we use to evaluate them include chronic liver disease (5.05), inflammatory bowel disease (5.06), and short bowel syndrome (5.07). We also use this body system to evaluate gastrointestinal hemorrhaging from any cause (5.02), malnutrition due to any digestive disorder (5.08), liver transplantation (5.09), small intestine transplantation (5.11), and pancreas transplantation (5.12). We evaluate cancers affecting the digestive system under the listings in 13.00.

B. *What evidence do we need to evaluate your digestive disorder?*

1. *General.* To establish that you have a digestive disorder, we need medical evidence about the existence of your digestive disorder and its severity. Medical evidence should include your medical history, physical examination findings, operative reports, and relevant laboratory findings.

2. *Laboratory findings.* We need laboratory reports such as results of imaging (see 5.00B3), endoscopy, and other diagnostic procedures. We may also need clinical laboratory and pathology results.

3. *Imaging* refers to medical imaging techniques, such as x-ray, ultrasound, magnetic resonance imaging, and computerized tomography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as a proper technique to support the evaluation of the disorder.

C. *What is chronic liver disease (CLD), and how do we evaluate it under 5.05?*

1. *General.* CLD is loss of liver function with cell necrosis (cell death), inflammation, or scarring of the liver that persists for more than 6 months. Common causes of CLD in adults include chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV), and prolonged alcohol abuse.

a. We will evaluate your signs of CLD, such as jaundice, changes in size of the liver and spleen, ascites, peripheral edema, or altered mental status. We will also evaluate your symptoms of CLD, such as pruritus (itching), fatigue, nausea, loss of appetite, or sleep disturbances when we assess the severity of your impairment(s) and how it affects your ability to function. In the absence of evidence of a chronic liver impairment, episodes of acute liver disease do not meet the requirements of 5.05.

b. *Laboratory findings* of your CLD may include decreased serum albumin, increased International Normalized Ratio (INR), arterial deoxygenation (hypoxemia), increased serum creatinine, oliguria (reduced urine output), or sodium retention. Another laboratory finding that may be included in the evidence is a liver biopsy. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy.

2. *Manifestations of CLD.*

a. *Gastrointestinal hemorrhaging* (5.05A), as a consequence of cirrhosis and high pressure in the liver's portal venous system, may occur from varices (dilated veins in the esophagus or the stomach) or from portal hypertensive gastropathy (abnormal mucosal changes in the stomach). When gastrointestinal hemorrhaging is due to a cause other than CLD, we evaluate it under 5.02. The phrase ''consider under a disability for 1 year'' in 5.02 and 5.05A does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

b. *Ascites or hydrothorax* (5.05B) is a pathologic accumulation of fluid in the peritoneal cavity (ascites) or pleural space (hydrothorax). Ascites or hydrothorax may be diagnosed by removing some of the fluid with needle aspiration (paracentesis or thoracentesis), physical examination, or imaging. The most common causes of ascites are portal hypertension and low serum albumin resulting from CLD. We evaluate other causes of ascites and hydrothorax that are unrelated to CLD, such as congestive heart failure and cancer, under the listings in the affected body systems.

c. *Spontaneous bacterial peritonitis (SBP)* (5.05C) is an acute bacterial infection of peritoneal fluid, and is most commonly associated with CLD. SBP is diagnosed by laboratory analysis of peritoneal fluid (obtained by paracentesis) that contains a neutrophil count (also called absolute neutrophil count) of at least 250 cells/mm^3. 5.05C is satisfied with one evaluation documenting peritoneal infection. We evaluate other causes of peritonitis that are unrelated to CLD, such as tuberculosis, malignancy, and perforated bowel, under the listings in the affected body systems.

d. *Hepatorenal syndrome* (5.05D) is renal failure associated with CLD in the absence of underlying kidney pathology. Findings associated with hepatorenal syndrome include elevation of serum creatinine, sodium retention with low urinary sodium excretion, and oliguria (reduced output of urine). We evaluate renal dysfunction with known underlying kidney pathology, such as glomerulonephritis, tubular necrosis, and renal infections under the listings in 6.00.

e. *Hepatopulmonary syndrome* (5.05E) is arterial deoxygenation (hypoxemia) due to intrapulmonary vascular dilation and arteriovenous shunting, associated with CLD. We evaluate pulmonary dysfunction with known underlying respiratory pathology, such as asthma, pneumonia, and pulmonary infections, under the listings in 3.00.

(i) Under 5.05E1, we require a resting arterial blood gas (ABG) measurement obtained while you are breathing room air; that is, without oxygen supplementation. The ABG report must include the P_aO_2 value, your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) We will not purchase the specialized imaging techniques described in 5.05E2; however, if you have had the test(s) at a time relevant to your claim, we will make every reasonable effort to obtain the report.

f. *Hepatic encephalopathy* (5.05F), also known as portosystemic encephalopathy, is a recurrent or chronic neuropsychiatric disorder associated with CLD.

(i) Under 5.05F2, we require documentation of a mental impairment associated with hepatic encephalopathy. A mental impairment can include abnormal behavior, changes in mental status, or an altered state of consciousness. Reports of abnormal behavior may show that you are experiencing delusions, paranoia, or hallucinations. Reports of changes in mental status may show change in sleep patterns, personality or mood changes, poor concentration, or poor judgment or cognitive dysfunction (for example, impaired memory, poor problem-solving ability, or attention deficits). Reports of altered state of consciousness may show that you are experiencing confusion, delirium, or stupor.

(ii) Signs and laboratory findings that document the severity of hepatic encephalopathy when not attributable to

other causes may include a ''flapping tremor'' (asterixis), characteristic abnormalities found on an electroencephalogram (EEG), or abnormal serum albumin or coagulation values. We will not purchase an EEG; however, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets the criteria of 5.05F.

(iii) We will not evaluate acute encephalopathy under 5.05F if it results from conditions other than CLD. For example, we will evaluate acute encephalopathy caused by vascular events under the listings in 11.00 and acute encephalopathy caused by cancer under the listings in 13.00.

3. *SSA CLD score* (5.05G). Listing 5.05G requires two SSA CLD scores, each requiring three laboratory values. The ''date of the SSA CLD score'' is the date of the earliest of the three laboratory values used for its calculation. The date of the second SSA CLD score must be at least 60 days after the date of the first SSA CLD score and both scores must be within the required 12-month period.

a. We calculate the SSA CLD score using a formula that includes three laboratory values: Serum creatinine (mg/dL), total bilirubin (mg/dL), and INR. The formula for the SSA CLD score calculation is:

$9.57 \times [\log_e(\text{serum creatinine mg/dL})] + 3.78 \times [\log_e(\text{serum total bilirubin mg/dL})] + 11.2 \times [\log_e(\text{INR})] + 6.43$

b. When we indicate ''$\log_e$'' (also abbreviated ''ln'') in the formula for the SSA CLD score calculation, we mean the ''base *e* logarithm'' or ''natural logarithm'' of the numerical laboratory value, not the ''base 10 logarithm'' or ''common logarithm'' (log) of the laboratory value, and not the actual laboratory value. For example, if a person has laboratory values of serum creatinine 2.0 mg/dL, serum total bilirubin 1.5 mg/dL, and INR 1.0, we compute the SSA CLD score as follows:

$9.57 \times [\log_e(\text{serum creatinine 2.0 mg/dL}) = 0.693] + 3.78 \times [\log_e(\text{serum total bilirubin 1.5 mg/dL}) = 0.405] + 11.2 \times [\log_e(\text{INR 1.0}) = 0] + 6.43$

$= 6.63 + 1.53 + 0 + 6.43$

$= 14.6$, which we round to an SSA CLD score of 15.

c. For any SSA CLD score calculation, all of the required laboratory values (serum creatinine, serum total bilirubin, and INR) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0 up to 1.0 to calculate your SSA CLD score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the *highest* value to calculate your SSA CLD score. If you are in renal failure or on dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine value of 4, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD calculation. We round the results of your SSA CLD score calculation to the nearest whole integer to arrive at your SSA CLD score.

D. *What is inflammatory bowel disease (IBD), and how do we evaluate it under 5.06?*

1. *IBD* is a group of inflammatory conditions of the small intestine and colon. The most common IBD disorders are Crohn's disease and ulcerative colitis. Remissions and exacerbations of variable duration are a hallmark of IBD.

2. We evaluate your signs and symptoms of IBD, such as diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, and palpable abdominal mass (usually inflamed loops of bowel), when we assess the severity of your impairment(s).

3. We consider other signs or laboratory findings of IBD that indicate malnutrition, such as anemia, edema, weight loss, or hypoalbuminemia, when we determine your ability to maintain adequate nutrition. We evaluate your inability to maintain adequate nutrition under 5.08.

4. *Repeated complications of IBD.*

a. Examples of complications of IBD include abscesses, intestinal perforation, toxic megacolon, infectious colitis, pyoderma gangrenosum, ureteral obstruction, primary sclerosing cholangitis, and hypercoagulable state (which may lead to thromboses or embolism). When we evaluate repeated complications of IBD, we consider all relevant information in your case record to determine the effects of your IBD on your ability to function independently, appropriately, effectively, and on a sustained basis. Factors we consider include, but are not limited to: Your symptoms, the frequency and duration of your complications, periods of exacerbation and remission, and the functional effects of your treatment, including the side effects of your medication. Your impairment will satisfy this criterion regardless of whether you have the same kind of complication repeatedly, all different complications, or any other combination of complications; for example, two of the same kind of complication and a different one.

b. To satisfy the requirements described under 5.06C, your IBD must result in repeated complications and marked limitation in one of three areas of functioning: Activities of daily living; maintaining social functioning; or completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace. If the complications do not last as long or occur as frequently as required under 5.06C, we will consider whether your IBD medically equals the listing.

c. *Marked* limitation means that the signs and symptoms of your IBD interfere *seriously* with your ability to function. Although we do not require the use of such a scale, ''marked'' would be the fourth point on a five-point rating scale consisting of no limitation, mild limitation, moderate limitation, marked limitation, and extreme limitation. We do not define ''marked'' by a specific number of activities of daily living or different behaviors in which your social functioning is impaired, or a specific number of tasks that you are able to complete, but by the nature and overall degree of interference with your functioning. You may have marked limitation when several activities or functions are impaired, or when only one is impaired. Additionally, you need not be totally precluded from performing an activity to have marked limitation, as long as the degree of limitation interferes seriously with your ability to function independently, appropriately, and effectively. The term ''marked'' does not imply that you must be confined to bed, hospitalized, or in a nursing home.

d. *Activities of daily living* include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, or paying bills. We will find that you have ''marked'' limitation in activities of daily living if you have a serious limitation in your ability to maintain a household or take public transportation because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to perform some self-care activities.

e. *Maintaining social functioning* includes the capacity to interact independently, appropriately, effectively, and on a sustained basis with others. It includes the ability to communicate effectively with others. We will find that you have ''marked'' limitation in maintaining social functioning if you have a serious limitation in social interaction on a sustained basis because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, or a pattern of exacerbation and remission, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to communicate with close friends or relatives.

f. *Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace* involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. We will find that you have ''marked'' limitation in completing tasks if you have a serious limitation in your ability to sustain concentration or pace adequate to complete work-related tasks because of symptoms, such as pain, severe fatigue, anxiety, or difficulty concentrating, caused by your IBD (including complications of the disorder) or its treatment, even if you are able to do some routine activities of daily living.

E. *What is short bowel syndrome (SBS), and how do we evaluate it under 5.07?*

1. *SBS* is a malabsorption disorder that occurs when ischemic vascular insults (caused, for example, by volvulus or necrotizing enterocolitis), trauma, or IBD complications require(s) surgical resection of any amount of the small intestine, resulting in chronic malnutrition.

2. We require a copy of the operative report that includes details of the surgical findings, or postoperative imaging indicating a resection of the small intestine. If we cannot get one of these reports, we need other medical reports that include details of the surgical findings. We also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

F. *How do we evaluate malnutrition due to any digestive disorder under 5.08?*

1. We evaluate malnutrition due to any digestive disorder using two body mass index (BMI) measurements at least 60 days apart in combination with an abnormal laboratory finding. If you have more than two BMI measurements within a consecutive 12-month period, we will use your two lowest BMI measurements that are at least 60 days apart.

2. BMI is the ratio of your weight to the square of your height.

a. We use measurements of your weight and height without shoes for these calculations.

b. We calculate BMI using one of the following formulas:

English Formula

BMI = [Weight in Pounds/(Height in Inches × Height in Inches)] × 703

Metric Formulas

BMI = Weight in Kilograms/(Height in Meters × Height in Meters)

BMI = [Weight in Kilograms/(Height in Centimeters × Height in Centimeters)] × 10,000

G. *How do we evaluate digestive organ transplantation?* If you receive a liver (5.09), small intestine (5.11), or pancreas (5.12) transplant, we will consider you to be disabled under the listing for 1 year from the date of the transplant. After that, we evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive digestive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase ''consider under a disability for 1 year'' in 5.09, 5.11, and 5.12 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

H. *How do we evaluate your digestive disorder if there is no record of ongoing treatment?* If there is no record of ongoing treatment despite the existence of a severe impairment(s), we will assess the severity and duration of your digestive disorder based on the current medical and other evidence in your case record. If there is no record of ongoing treatment, you may not be able to show an impairment that meets a digestive disorders listing, but your impairment may medically equal a listing, or be disabling based on consideration of your residual functional capacity, age, education, and work experience.

I. *How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?* If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability. See § 404.1535 and § 416.935 of this chapter. Digestive disorders resulting from drug or alcohol use are often chronic in nature and will not necessarily improve with cessation in drug or alcohol use.

J. *How do we evaluate digestive disorders that do not meet one of these listings?*

1. These listings are only examples of common digestive disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 404.1526 and § 416.926 of this chapter. Digestive disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in § 404.1520 and § 416.920 of this chapter. We use the rules in § 404.1594 and § 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

5.01 Category of Impairments, Digestive Disorders

5.02 *Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions* of at least 2 units of blood per transfusion, within a consecutive 12-month period and at least 30 days apart. Consider under a disability for 1 year following the last documented transfusion; after that, evaluate the residual impairment(s).

5.03–5.04 [Reserved]

5.05 *Chronic liver disease (CLD)* (see 5.00C) with A, B, C, D, E, F, or G:

A. Hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy (see 5.00C2a), documented by imaging (see 5.00B3); resulting in hemodynamic instability indicated by signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down, or syncope (fainting); and requiring hospitalization for transfusion of at least two units of blood. Consider under a disability for 1 year following the documented transfusion; after that, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes (see 5.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:

1. Paracentesis; or

2. Thoracentesis; or

3. Imaging or physical examination with a or b:

a. Serum albumin of 3.0 g/dL or less; or

b. INR of at least 1.5.

OR

C. Spontaneous bacterial peritonitis (see 5.00C2c) documented by peritoneal fluid containing a neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome (see 5.00C2d) documented by 1, 2, or 3:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 500 mL; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome (see 5.00C2e) documented by 1 or 2:

1. Arterial P_aO_2 measured by an ABG test, while at rest, breathing room air, less than or equal to:

a. 60 mm Hg, at test sites less than 3,000 feet above sea level; or

b. 55 mm Hg, at test sites from 3,000 through 6,000 feet above sea level; or

c. 50 mm Hg, at test sites over 6,000 feet above sea level; or

2. Intrapulmonary arteriovenous shunting as shown by contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy (see 5.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2:

1. History of transjugular intrahepatic portosystemic shunt (TIPS) or other surgical portosystemic shunt; or

2. One of the following on at least two evaluations at least 60 days apart within the same consecutive 12-month period as in F:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. EEG demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. INR of 1.5 or greater.

OR

G. Two SSA CLD scores (see 5.00C3) of at least 20 within a consecutive 12-month period and at least 60 days apart.

5.06 *Inflammatory bowel disease (IBD)* (see 5.00D) documented by endoscopy, biopsy, imaging, or operative findings, *and* demonstrated by A, B, or C:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart.

OR

B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:

1. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or

2. Perineal disease with a draining abscess or fistula; or

3. Need for supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter.

OR

C. Repeated complications of IBD (see 5.00D4a), occurring an average of three times a year, or once every 4 months, each lasting 2 weeks or more, within a consecutive 12-month period, and marked limitation (see 5.00D4c) in one of the following:

1. Activities of daily living (see 5.00D4d); or

2. Maintaining social functioning (see 5.00D4e); or

3. Completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace (see 5.00D4f).

5.07 *Short bowel syndrome (SBS)* (see 5.00E) due to surgical resection of any amount of the small intestine, resulting in dependence on daily parenteral nutrition via a central venous catheter.

5.08 *Malnutrition due to any digestive disorder* (see 5.00F), documented by A and B:

A. One of the following:

1. Anemia with hemoglobin of less than 10.0 g/dL, present on two evaluations within a consecutive 12-month period and at least 60 days apart; or

2. Serum albumin of 3.0 g/dL or less, present on two evaluations within a consecutive 12-month period and at least 60 days apart.

AND

B. Two BMI measurements of less than 18.0 (see 5.00F2) within a consecutive 12-month period and at least 60 days apart.

5.09 *Liver transplantation* (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

5.10 [Reserved]

5.11 *Small intestine transplantation* (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

5.12 *Pancreas transplantation* (see 5.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

* * * * *

8.00 Skin Disorders

A. *Which skin disorders do we evaluate under these listings?* We use these listings to evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. We evaluate genetic photosensitivity disorders (8.07), burns (8.08), and chronic conditions of the skin or mucous membranes such as ichthyosis, bullous disease, dermatitis, psoriasis, and hidradenitis suppurativa (8.09).

B. *What are our definitions for the following terms used in this body system?*

1. *Assistive device(s):* An assistive device, for the purposes of these listings, is any device used to improve stability, dexterity, or mobility. An assistive device can be hand-held, such as a cane(s), a crutch(es), or a walker; or worn, such as a prosthesis or an orthosis.

2. *Chronic skin lesions:* Chronic skin lesions can have recurrent exacerbations. They can occur despite prescribed medical treatment. These chronic skin lesions can develop on any part of your body, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Chronic skin lesions may result in functional limitations as described in 8.00D2.

3. *Contractures:* Contractures are permanent fibrous scar tissue resulting in tightening and thickening of skin that prevents normal movement of the damaged area. They can develop on any part of your musculoskeletal system, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Contractures may result in functional limitations as described in 8.00D2.

4. *Documented medical need:* When we use the term ''documented medical need,'' we mean that there is evidence from your medical source(s) in the medical record that supports your need for an assistive device (see § 404.1513 and § 416.913 of this chapter). The evidence must include documentation from your medical source(s) describing any limitation(s) in your upper or lower extremity functioning that supports your need for the assistive device, and describing the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

5. *Fine and gross movements:* Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional activities such as lifting, carrying, pushing, and pulling.

6. *Surgical management:* For the purposes of these listings, surgical management includes the surgery(-ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

C. *What evidence do we need to evaluate your skin disorder?*

1. To establish the presence of a skin disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source who has examined you for the disorder.

2. We will make every reasonable effort to obtain your medical history, treatment records, and relevant laboratory findings, but we will not purchase genetic testing.

3. When we evaluate the presence and severity of your skin disorder(s), we generally need information regarding:

a. The onset, duration, and frequency of exacerbations;

b. The prognosis of your skin disorder;

c. The location, size, and appearance of lesions and contractures;

d. Your history of familial incidence; exposure to toxins, allergens or irritants; seasonal variations; and stress factors;

e. Your ability to function outside of a highly protective environment;

f. Laboratory findings (for example, a biopsy obtained independently of Social Security disability evaluation or results of blood tests);

g. Evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice; and

h. Statements you or others make about your disorder(s), your restrictions, and your daily activities.

D. *How do we evaluate the severity of skin disorders?*

1. *General.* We evaluate the severity of skin disorders based on the site(s) of your chronic skin lesions or contractures, functional limitations caused by your signs and symptoms (including pain) (see 8.00D2), and how your prescribed treatment affects you. We consider the frequency and severity of your exacerbations, how quickly they resolve, and how you function between exacerbations, to determine whether your skin disorder meets or medically equals a listing. If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 8.00D6. We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 404.1512, 404.1513, and 404.1520b and §§ 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating your symptoms, see § 404.1529 and § 416.929 of this chapter.

2. *Limitation(s) of physical functioning due to skin disorders.*

a. Skin disorders may be due to chronic skin lesions (see 8.00B2) or contractures (see 8.00B3), and may cause pain or restrict movement, which can limit your ability to initiate, sustain, and complete work-related activities. For example, skin lesions in the axilla may limit your ability to raise or reach with the affected arm, or lesions in the inguinal region may limit your ability to ambulate, sit, or lift and carry. To evaluate your skin disorder(s) under 8.07B, 8.08, and 8.09, we require medically documented evidence of physical limitation(s) of functioning related to your disorder. The decrease in physical function must have lasted, or can be expected to last, for a continuous period of at least 12 months (see § 404.1509 and § 416.909 of this chapter). Xeroderma pigmentosum is the only skin disorder that does not include functional criteria because the characteristics and severity of the disorder itself are sufficient to meet the criteria in 8.07A.

b. The functional criteria require impairment-related physical limitations in using upper or lower extremities that have lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

(i) Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete

work-related activities involving fine and gross movements;

(ii) Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements due to chronic skin lesions or contractures, and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

(iii) Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

(iv) Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

3. *Frequency of exacerbations due to chronic skin lesions.* A skin disorder resulting in chronic skin lesions (see 8.00B2) may have frequent exacerbations severe enough to meet a listing even if each individual skin lesion exacerbation did not last for an extended amount of time. We will consider the frequency, severity, and duration of skin lesion exacerbations; how quickly they resolve; and how you function in the time between skin lesion exacerbations, to determine whether your skin disorder meets or equals a listing.

4. *Symptoms (including pain).* Your symptoms may be an important factor in our determination of whether your skin disorder(s) meets or medically equals a listing, or whether you are otherwise able to work. We consider your symptoms only when you have a medically determinable impairment that could reasonably be expected to produce the symptoms. See § 404.1529 and § 416.929 of this chapter.

5. *Treatment.*

a. *General.* Treatments for skin disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. Your skin disorder's response to treatment may vary due to treatment resistance or side effects that can result in functional limitations. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your skin disorder, and on your ability to function.

b. *Despite adherence to prescribed medical treatment for 3 months.* Under 8.09, we require that your symptoms persist ''despite adherence to prescribed medical treatment for 3 months.'' This requirement means that you must have taken prescribed medication(s) or followed other medical treatment prescribed by a physician for 3 consecutive months. Treatment or effects of treatment may be temporary. In most cases, sufficient time must elapse to allow us to evaluate your response to treatment, including any side effects. For our purposes, ''sufficient time'' means a period of at least 3 months. If your treatment has not lasted for at least 3 months, we will follow the rules in 8.00D6a. To evaluate the severity of physical limitations due to your skin disorder(s), we require medically documented evidence of disorder-related physical limitation(s) of functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months. See § 404.1509 and § 416.909 of this chapter. The 3 months adherence to prescribed medical treatment must be within the period of at least 12 months that we use to evaluate severity.

c. *Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics.* If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another basis.

6. *No record of ongoing treatment.*

a. Despite having a skin disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal medical record for us to review when we evaluate your disorder. In some instances, we may be able to assess the severity and duration of your skin disorder based on your medical record and current evidence alone. We may ask you to attend a consultative examination to determine the severity and potential duration of your skin disorder (see § 404.1519a and § 416.919a of this chapter).

b. If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 8.09. If the information in your case record is not sufficient to show that you have a skin disorder that meets the criteria of one of the skin disorders listings, we will follow the rules in 8.00I.

E. *How do we evaluate genetic photosensitivity disorders under 8.07?* Genetic photosensitivity disorders are disorders of the skin caused by an increase in the sensitivity of the skin to sources of ultraviolet light, including sunlight.

1. *Xeroderma pigmentosum (XP) (8.07A).* XP is a genetic photosensitivity disorder with lifelong hypersensitivity to all forms of ultraviolet light. Laboratory testing confirms the diagnosis by documenting abnormalities in the body's ability to repair DNA (deoxyribonucleic acid) mutations after ultraviolet light exposure. Your skin disorder meets the requirements of 8.07A if you have clinical and laboratory findings supporting a diagnosis of XP (see 8.00E3).

2. *Other genetic photosensitivity disorders (8.07B).* The effects of other genetic photosensitivity disorders may vary and may not persist over time. To meet the requirements of 8.07B, a genetic photosensitivity disorder other than XP must be established by clinical and laboratory findings (see 8.00C) and must result either in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that result in functional limitations (see 8.00D), or must result in the inability to function outside of a highly protective environment. Some genetic photosensitivity disorders can have very serious effects on other body systems, especially special senses and speech, neurological, mental, and cancer. We will evaluate your disorder(s) under the listings in 2.00, 11.00, 12.00, or 13.00, as appropriate.

3. *What evidence do we need to document that you have XP or another genetic photosensitivity disorder?* We will make a reasonable effort to obtain evidence of your disorder(s), but we will not purchase genetic testing. When the results of genetic tests are part of the existing evidence in your case record, we will evaluate the test results with all other relevant evidence. We need the following clinical and laboratory findings to document that you have XP or another genetic photosensitivity disorder:

a. A laboratory report of a definitive genetic laboratory test documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder, signed by an acceptable medical source (AMS); or

b. A laboratory report of a definitive test that is not signed by an AMS, and a report from an AMS stating that you have undergone definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder; or

c. If we do not have a laboratory report of a definitive test, we need documentation from an AMS that an appropriate laboratory analysis or other diagnostic method(s) confirms a positive diagnosis of your skin disorder. This documentation must state that you had the appropriate definitive laboratory test(s) for diagnosing your disorder and provide the results, or explain how another diagnostic method(s), consistent with the prevailing state of medical knowledge and clinical practice, established your diagnosis.

4. *Inability to function outside of a highly protective environment* means that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from similar unshielded light sources), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects.

F. *How do we evaluate burns under 8.08?*

1. Electrical, chemical, or thermal burns frequently affect other body systems, for example, *musculoskeletal, special senses and speech, respiratory, cardiovascular, genitourinary, neurological,* or *mental.* We evaluate burns in the same way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your disorder. For example, if your soft tissue injuries resulting from burns are under surgical management (as defined in 8.00B6), we will evaluate your disorder under the listings in 1.00.

2. We evaluate third-degree burns resulting in contractures (see 8.00B3) that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, under 8.08. To be

disabling, these burns must result in functional limitation(s) (see 8.00D2) that has lasted or can be expected to last for a continuous period of at least 12 months.

G. *How do we evaluate chronic conditions of the skin or mucous membranes under 8.09?* We evaluate skin disorders that result in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) under 8.09. These disorders must result in chronic skin lesions or contractures that continue to persist despite adherence to prescribed medical treatment for 3 months (see 8.00D5b) and cause functional limitations (see 8.00D2). Examples of skin disorders evaluated under this listing are ichthyosis, bullous diseases (such as pemphigus, epidermolysis bullosa, and dermatitis herpetiformis), chronic skin infections, dermatitis, psoriasis, and hidradenitis suppurativa.

H. *How do we evaluate disorders in other body systems that affect the skin?* When your disorder(s) in another body system affects the skin, we first evaluate the predominant feature of your disorder(s) under the appropriate body system. Examples of disorders in other body systems that may affect the skin include the following:

1. *Diabetes mellitus.* Diabetes mellitus that is not well controlled, despite treatment, can cause chronic hyperglycemia resulting in serious, long-lasting or recurrent exacerbations or complications. We evaluate those exacerbations or complications under the affected body system(s). If the complication involves soft tissue or amputation(s), we evaluate these features under the listings in 1.00. If the exacerbations or complications involve chronic bacterial or fungal skin lesions resulting from diabetes mellitus, we evaluate your limitations from the skin disorder under listing 8.09.

2. *Tuberous sclerosis.* The predominant functionally limiting features of tuberous sclerosis are seizures and intellectual disability or other mental disorders. We evaluate these features under the listings in 11.00 or 12.00, as appropriate.

3. *Malignant tumors of the skin.* Malignant tumors of the skin (for example, malignant melanomas) are cancers, or malignant neoplastic diseases, that we evaluate under the listings in 13.00.

4. *Immune system disorders.* We evaluate skin manifestations of immune system disorders such as systemic lupus erythematosus, scleroderma, psoriasis, and human immunodeficiency virus (HIV) infection under the listings in 14.00.

5. *Head or facial disfigurement or deformity, and other physical deformities caused by skin disorders.* A head or facial disfigurement or deformity may result in loss of your sight, hearing, speech, or ability to chew. In addition to head and facial disfigurement and deformity, other physical deformities may result in associated psychological problems (for example, depression). We evaluate the effects of head or facial disfigurement or deformity, or other physical deformities caused by skin disorders under the listings in 1.00, 2.00, 5.00, or 12.00, as appropriate.

I. *How do we evaluate skin disorders that do not meet one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 404.1526 and § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in § 404.1520 and § 416.920 of this chapter. We use the rules in § 404.1594 and § 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

8.01 Category of Impairments, Skin Disorders

8.02–8.06 [Reserved]

8.07 *Genetic photosensitivity disorders,* established as described in 8.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied.

A. Xeroderma pigmentosum (see 8.00E1).

OR

B. Other genetic photosensitivity disorders (see 8.00E2) with either 1 or 2:

1. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that cause an inability to function outside of a highly protective environment (see 8.00E4); or

2. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that cause functional limitations (see 8.00D2) due to limitation(s) from your skin condition, such as pain, as evidenced by:

a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements; or

b. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

c. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when limitations are due to involvement of the perineum or the inguinal region); or

d. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

8.08 *Burns* (see 8.00F). Third-degree burns that do not require continuing surgical management, or that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, resulting in chronic skin lesions (see 8.00B2) or contractures (see 8.00B3) that cause functional limitations (see 8.00D2) due to limitation(s), such as pain, from your skin condition, as evidenced by:

A. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements.

OR

B. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity.

OR

C. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

OR

D. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

8.09 *Chronic conditions of the skin or mucous membranes* (see 8.00G) resulting in:

A. Chronic skin lesions (see 8.00B2) or contractures (see 8.00B3); chronic pain; or other physical limitation(s); that persist despite adherence to prescribed medical treatment for 3 months (see 8.00D5b), causing functional limitations (see 8.00D2) due to limitation(s), such as pain, from your skin condition.

AND

B. Impairment-related significant limitation demonstrated by 1, 2, 3, or 4:

1. An inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete work-related activities involving fine and gross movements; or

2. Inability to use one upper extremity to independently initiate, sustain, and complete work-related activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

3. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

4. Inability to maintain an upright position while standing or walking, to independently

initiate, sustain, and complete work-related activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to the involvement of the perineum or the inguinal region).

* * * * *

Part B

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105.00 Digestive Disorders

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105.00 Digestive Disorders

A. *Which digestive disorders do we evaluate in this body system?* We evaluate digestive disorders that result in severe dysfunction of the liver, pancreas, and gastrointestinal tract (the large, muscular tube that extends from the mouth to the anus, where the movement of muscles, along with the release of hormones and enzymes, allows for the digestion of food) in this body system. Examples of such disorders and the listings we use to evaluate them include chronic liver disease (105.05), inflammatory bowel disease (105.06), and short bowel syndrome (105.07). We also use this body system to evaluate gastrointestinal hemorrhaging from any cause (105.02), growth failure due to any digestive disorder (105.08), liver transplantation (105.09), need for supplemental daily enteral feeding via a gastrostomy due to any cause for children who have not attained age 3 (105.10), small intestine transplantation (105.11), and pancreas transplantation (105.12). We evaluate cancers affecting the digestive system under the listings in 113.00.

B. *What evidence do we need to evaluate your digestive disorder?*

1. *General.* To establish that you have a digestive disorder, we need medical evidence about the existence of your digestive disorder and its severity. Medical evidence should include your medical history, physical examination findings, operative reports, and relevant laboratory findings.

2. *Laboratory findings.* We need laboratory reports such as results of imaging (see 105.00B3), endoscopy, and other diagnostic procedures. We may also need clinical laboratory and pathology results.

3. *Imaging* refers to medical imaging techniques, such as x-ray, ultrasound, magnetic resonance imaging, and computerized tomography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as a proper technique to support the evaluation of the disorder.

C. *What is chronic liver disease (CLD), and how do we evaluate it under 105.05?*

1. *General.* CLD is loss of liver function with cell necrosis (cell death), inflammation, or scarring of the liver that persists for more than 6 months. Common causes of CLD in children include chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV), autoimmune hepatitis, and metabolic disease.

a. We will evaluate your signs of CLD, such as jaundice, changes in size of the liver and spleen, ascites, peripheral edema, or altered mental status. We will also evaluate your symptoms of CLD, such as pruritus (itching), fatigue, nausea, loss of appetite, or sleep disturbances when we assess the severity of your impairment(s) and how it affects your ability to function. In the absence of evidence of a chronic liver impairment, episodes of acute liver disease do not meet the requirements of 105.05.

b. *Laboratory findings* of your CLD may include decreased serum albumin, increased International Normalized Ratio (INR), arterial deoxygenation (hypoxemia), increased serum creatinine, oliguria (reduced urine output), or sodium retention. Another laboratory finding that may be included in the evidence is a liver biopsy. If you have had a liver biopsy, we will make every reasonable effort to obtain the results; however, we will not purchase a liver biopsy.

2. *Manifestations of CLD.*

a. *Gastrointestinal hemorrhaging* (105.05A), as a consequence of cirrhosis and high pressure in the liver's portal venous system, may occur from varices (dilated veins in the esophagus or the stomach) or from portal hypertensive gastropathy (abnormal mucosal changes in the stomach). When gastrointestinal hemorrhaging is due to a cause other than CLD, we evaluate it under 105.02. The phrase ''consider under a disability for 1 year'' in 105.02 and 105.05A does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

b. *Ascites or hydrothorax* (105.05B) is a pathologic accumulation of fluid in the peritoneal cavity (ascites) or pleural space (hydrothorax). Ascites or hydrothorax may be diagnosed by removing some of the fluid with needle aspiration (paracentesis or thoracentesis), physical examination, or imaging. The most common causes of ascites are portal hypertension and low serum albumin resulting from CLD. We evaluate other causes of ascites and hydrothorax that are unrelated to CLD, such as congestive heart failure and cancer, under the listings in the affected body systems.

c. *Spontaneous bacterial peritonitis (SBP)* (105.05C) is an acute bacterial infection of peritoneal fluid, and is most commonly associated with CLD. SBP is diagnosed by laboratory analysis of peritoneal fluid (obtained by paracentesis) that contains a neutrophil count (also called absolute neutrophil count) of at least 250 cells/mm^3. 105.05C is satisfied with one evaluation documenting peritoneal infection. We evaluate other causes of peritonitis that are unrelated to CLD, such as tuberculosis, malignancy, and perforated bowel, under the listings in the affected body systems.

d. *Hepatorenal syndrome* (105.05D) is renal failure associated with CLD in the absence of underlying kidney pathology. Findings associated with hepatorenal syndrome include elevation of serum creatinine, sodium retention with low urinary sodium excretion, and oliguria (reduced output of urine). We evaluate renal dysfunction with known underlying kidney pathology, such as glomerulonephritis, tubular necrosis, and renal infections under the listings in 106.00.

e. *Hepatopulmonary syndrome* (105.05E) is arterial deoxygenation (hypoxemia) due to intrapulmonary vascular dilation and arteriovenous shunting, associated with CLD. We evaluate pulmonary dysfunction with known underlying respiratory pathology, such as asthma, pneumonia, and pulmonary infections, under the listings in 103.00.

(i) Under 105.05E1, we require a resting arterial blood gas (ABG) measurement obtained while you are breathing room air; that is, without oxygen supplementation. The ABG report must include the P_aO_2 value, your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) We will not purchase the specialized imaging techniques described in 105.05E2; however, if you have had the test(s) at a time relevant to your claim, we will make every reasonable effort to obtain the report.

f. *Hepatic encephalopathy* (105.05F), also known as portosystemic encephalopathy, is a recurrent or chronic neuropsychiatric disorder associated with CLD.

(i) Under 105.05F2, we require documentation of a mental impairment associated with hepatic encephalopathy. A mental impairment can include abnormal behavior, changes in mental status, or an altered state of consciousness. Reports of abnormal behavior may show that you are experiencing delusions, paranoia, or hallucinations. Reports of changes in mental status may show change in sleep patterns, personality or mood changes, poor concentration, or poor judgment or cognitive dysfunction (for example, impaired memory, poor problem-solving ability, or attention deficits). Reports of altered state of consciousness may show that you are experiencing confusion, delirium, or stupor.

(ii) Signs and laboratory findings that document the severity of hepatic encephalopathy when not attributable to other causes may include a ''flapping tremor'' (asterixis), characteristic abnormalities found on an electroencephalogram (EEG), or abnormal serum albumin or coagulation values. We will not purchase an EEG; however, if you have had this test at a time relevant to your claim, we will make every reasonable effort to obtain the report for the purpose of establishing whether your impairment meets the criteria of 105.05F.

(iii) We will not evaluate acute encephalopathy under 105.05F if it results from conditions other than CLD. For example, we will evaluate acute encephalopathy caused by vascular events under the listings in 111.00 and acute encephalopathy caused by cancer under the listings in 113.00.

3. *SSA CLD and SSA CLD–P scores* (105.05G). Listing 105.05G1 requires two SSA CLD scores, each requiring three laboratory values, or two SSA CLD–P scores, each requiring four parameters (three laboratory values and growth failure). The ''date of the SSA CLD score'' is the date of the earliest of the three laboratory values used for its calculation. The ''date of the SSA CLD–P score'' is the date of the earliest of the three laboratory values used for its calculation. For 105.05G1, the date of the second SSA CLD or SSA CLD–P score must

be at least 60 days after the date of the first SSA CLD or SSA CLD–P score and both scores must be within the required 12-month period. Listing 105.05G2 requires one SSA CLD–P score.

a. *SSA CLD score.*

(i) We calculate the SSA CLD score using a formula that includes three laboratory values: Serum creatinine (mg/dL), total bilirubin (mg/dL), and INR. The formula for the SSA CLD score calculation is:

$9.57 \times [\log_e(\text{serum creatinine mg/dL})] + 3.78 \times [\log_e(\text{serum total bilirubin mg/dL})] + 11.2 \times [\log_e(\text{INR})] + 6.43$

(ii) When we indicate ''$\log_e$'' (also abbreviated ''ln'') in the formula for the SSA CLD score calculation, we mean the ''base *e* logarithm'' or ''natural logarithm'' of the numerical laboratory value, not the ''base 10 logarithm'' or ''common logarithm'' (log) of the laboratory value, and not the actual laboratory value. For example, if a person has laboratory values of serum creatinine 2.0 mg/dL, serum total bilirubin 1.5 mg/dL, and INR 1.0, we compute the SSA CLD score as follows:

$9.57 \times [\log_e(\text{serum creatinine 2.0 mg/dL}) = 0.693] + 3.78 \times [\log_e(\text{serum total bilirubin 1.5 mg/dL}) = 0.405] + 11.2 \times [\log_e(\text{INR 1.0}) = 0] + 6.43$

$= 6.63 + 1.53 + 0 + 6.43$

$= 14.6$, which we round to an SSA CLD score of 15.

(iii) For an SSA CLD score calculation, all of the required laboratory values (serum creatinine, serum total bilirubin, and INR) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0 up to 1.0 to calculate your SSA CLD score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the *highest* value to calculate your SSA CLD score. If you are in renal failure or on dialysis within a week of any serum creatinine test in the period used for the SSA CLD calculation, we will use a serum creatinine value of 4, which is the maximum serum creatinine level allowed in the calculation, to calculate your SSA CLD score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD calculation. We round the results of your SSA CLD score calculation to the nearest whole integer to arrive at your SSA CLD score.

b. *SSA CLD–P score*

(i) We calculate the SSA CLD–P scores using a formula that includes four parameters: Serum total bilirubin (mg/dL), INR, serum albumin (g/dL), and whether you have growth failure. The formula for the SSA CLD–P score calculation is:

$4.80 \times [\log_e(\text{serum total bilirubin mg/dL})] + 18.57 \times [\log_e(\text{INR})] - 6.87 \times [\log_e(\text{serum albumin g/dL})] + 6.67$ if you have growth failure (< -2 standard deviations for weight or height)

(ii) When we indicate ''$\log_e$'' in the formula for the SSA CLD–P score calculation, we mean the ''base *e* logarithm'' or ''natural logarithm'' ($\log_e$) of a numerical laboratory value, not the ''base 10 logarithm'' or ''common logarithm'' (log) of the laboratory value, and not the actual laboratory value. For example, if a female child is 4.0 years old, has growth failure, and has laboratory values of serum total bilirubin 2.2 mg/dL, INR 1.0, and serum albumin 3.5 g/dL, we compute the SSA CLD–P score as follows:

$4.80 \times [\log_e(\text{serum total bilirubin 2.2 mg/dL}) = 0.788] + 18.57 \times [\log_e(\text{INR 1.0}) = 0] - 6.87 \times [\log_e(\text{serum albumin 3.5 g/dL}) = 1.253] + 6.67$

$= 3.78 + 0 - 8.61 + 6.67$

$= 1.84$, which we round to an SSA CLD–P score of 2.

(iii) For an SSA CLD–P score calculation, all of the required laboratory values (serum total bilirubin, INR, and serum albumin) must have been obtained within a continuous 30-day period. We round any of the required laboratory values less than 1.0 up to 1.0 to calculate your SSA CLD–P score. If there are multiple laboratory values within the 30-day interval for any given laboratory test, we use the *highest* serum total bilirubin and INR values and the *lowest* serum albumin value to calculate the SSA CLD–P score. We will not use any INR values derived from testing done while you are on anticoagulant treatment in our SSA CLD–P calculation. We will not purchase INR values for children who have not attained age 12. If there is no INR value for a child under 12 within the applicable period, we will use an INR value of 1.1 to calculate the SSA CLD–P score. We round the results of your SSA CLD–P score calculation to the nearest whole integer to arrive at your SSA CLD–P score.

(iv) The weight and length/height measurements used for the calculation must be obtained within the same 30-day period as the laboratory values.

4. *Extrahepatic biliary atresia* (105.05H) presents itself in the first 2 months of life with persistent jaundice. To satisfy 105.05H, the diagnosis of extrahepatic biliary atresia must be confirmed by liver biopsy or intraoperative cholangiogram that shows obliteration of the extrahepatic biliary tree. Biliary atresia is usually treated surgically by portoenterostomy (for example, Kasai procedure). If this surgery is not performed in the first months of life or is not completely successful, liver transplantation is indicated. If you have received a liver transplant, we will evaluate your impairment under 105.09. The phrase ''consider under a disability for 1 year'' in 105.05H does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

D. *What is inflammatory bowel disease (IBD), and how do we evaluate it under 105.06?*

1. *IBD* is a group of inflammatory conditions of the small intestine and colon. The most common IBD disorders are Crohn's disease and ulcerative colitis. Remissions and exacerbations of variable duration are a hallmark of IBD.

2. We evaluate your signs and symptoms of IBD, such as diarrhea, fecal incontinence, rectal bleeding, abdominal pain, fatigue, fever, nausea, vomiting, arthralgia, abdominal tenderness, and palpable abdominal mass (usually inflamed loops of bowel), when we assess the severity of your impairment(s).

3. We consider other signs or laboratory findings of IBD that indicate malnutrition, such as anemia, edema, weight loss, or hypoalbuminemia, when we determine your ability to maintain adequate nutrition. We evaluate your inability to maintain adequate nutrition under 105.08.

4. Examples of complications of IBD that may result in hospitalization include abscesses, intestinal perforation, toxic megacolon, infectious colitis, pyoderma gangrenosum, ureteral obstruction, primary sclerosing cholangitis, and hypercoagulable state (which may lead to thromboses or embolism). The three hospitalizations in 105.06C do not have to be for the same complication of IBD.

E. *What is short bowel syndrome (SBS), and how do we evaluate it under 105.07?*

1. *SBS* is a malabsorption disorder that occurs when congenital intestinal abnormalities, ischemic vascular insults (caused, for example, by volvulus or necrotizing enterocolitis), trauma, or IBD complications require(s) surgical resection of any amount of the small intestine, resulting in chronic malnutrition.

2. We require a copy of the operative report that includes details of the surgical findings, or postoperative imaging indicating a resection of the small intestine. If we cannot get one of these reports, we need other medical reports that include details of the surgical findings. We also need medical documentation that you are dependent on daily parenteral nutrition to provide most of your nutritional requirements.

F. *How do we evaluate growth failure due to any digestive disorder under 105.08?*

1. To evaluate growth failure due to any digestive disorder, we require documentation of the laboratory findings of chronic nutritional deficiency described in 105.08A and the growth measurements in 105.08B within the same consecutive 12-month period. The dates of laboratory findings may be different from the dates of growth measurements.

2. Under 105.08B, we evaluate a child's growth failure by using the appropriate table for age and gender.

a. For children from birth to attainment of age 2, we use the weight-for-length table (see Table I or Table II).

b. For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table (see Table III or Table IV).

c. BMI is the ratio of your weight to the square of your height. We calculate BMI using one of the following formulas:

English Formula

$\text{BMI} = [\text{Weight in Pounds}/(\text{Height in Inches} \times \text{Height in Inches})] \times 703$

Metric Formulas

$\text{BMI} = \text{Weight in Kilograms}/(\text{Height in Meters} \times \text{Height in Meters})$

$\text{BMI} = [\text{Weight in Kilograms}/(\text{Height in Centimeters} \times \text{Height in Centimeters})] \times 10{,}000$

G. *How do we evaluate digestive organ transplantation?* If you receive a liver (105.09), small intestine (105.11), or pancreas

(105.12) transplant, we will consider you to be disabled under the listing for 1 year from the date of the transplant. After that, we evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive digestive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase ''consider under a disability for 1 year'' in 105.09, 105.11, and 105.12 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We determine the onset of your disability based on the facts of your case.

H. *How do we evaluate the need for supplemental daily enteral feeding via a gastrostomy?* We evaluate the need for supplemental daily enteral feeding via a gastrostomy in children who have not attained age 3 under 105.10 regardless of the medical reason for the gastrostomy. After a child attains age 3, we evaluate growth failure due to any digestive disorder under 105.08, IBD requiring supplemental daily enteral or parenteral nutrition under 105.06, or other medical or developmental disorders under another digestive disorders listing or under a listing in an affected body system(s).

I. *How do we evaluate esophageal stricture or stenosis?* Esophageal stricture or stenosis (narrowing) from congenital atresia (absence or abnormal closure of a tubular body organ) or destructive esophagitis may result in malnutrition or the need for gastrostomy placement, which we evaluate under 105.08 or 105.10. Esophageal stricture or stenosis may also result in complications such as pneumonias due to frequent aspiration, or difficulty in maintaining nutritional status short of listing level severity. While these individual complications usually do not meet the listing criteria, a combination of your impairments may medically equal a listing or functionally equal the listings.

J. *How do we evaluate your digestive disorder if there is no record of ongoing treatment?* If there is no record of ongoing treatment despite the existence of a severe impairment(s), we will assess the severity and duration of your digestive disorder based on the current medical and other evidence in your case record. If there is no record of ongoing treatment, you may not be able to show an impairment that meets a digestive disorders listing, but your impairment may medically equal a listing, or be disabling based on our rules of functional equivalence.

K. *How do we evaluate your digestive disorder if there is evidence establishing a substance use disorder?* If we find that you are disabled and there is medical evidence in your case record establishing that you have a substance use disorder, we will determine whether your substance use disorder is a contributing factor material to the determination of disability. See § 416.935 of this chapter. Digestive disorders resulting from drug or alcohol use are often chronic in nature and will not necessarily improve with cessation in drug or alcohol use.

L. *How do we evaluate digestive disorders that do not meet one of these listings?*

1. These listings are only examples of common digestive disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. Digestive disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, we will also consider whether it functionally equals the listings. See § 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

105.01 Category of Impairments, Digestive Disorders

105.02 *Gastrointestinal hemorrhaging from any cause, requiring three blood transfusions* of at least 10 cc of blood/kg of body weight per transfusion, within a consecutive 12-month period and at least 30 days apart. Consider under a disability for 1 year following the last documented transfusion; after that, evaluate the residual impairment(s).

105.03–105.04 [Reserved]

105.05 *Chronic liver disease (CLD)* (see 105.00C) with A, B, C, D, E, F, G, or H:

A. Hemorrhaging from esophageal, gastric, or ectopic varices, or from portal hypertensive gastropathy (see 105.00C2a), documented by imaging (see 105.00B3); resulting in hemodynamic instability indicated by signs such as pallor (pale skin), diaphoresis (profuse perspiration), rapid pulse, low blood pressure, postural hypotension (pronounced fall in blood pressure when arising to an upright position from lying down, or syncope (fainting); and requiring hospitalization for transfusion of at least 10 cc of blood/kg of body weight. Consider under a disability for 1 year following the documented transfusion; after that, evaluate the residual impairment(s).

OR

B. Ascites or hydrothorax not attributable to other causes (see 105.00C2b), present on two evaluations within a consecutive 12-month period and at least 60 days apart. Each evaluation must document the ascites or hydrothorax by 1, 2, or 3:

1. Paracentesis; or

2. Thoracentesis; or

3. Imaging or physical examination with a or b:

a. Serum albumin of 3.0 g/dL or less; or

b. INR of at least 1.5.

OR

C. Spontaneous bacterial peritonitis (see 105.00C2c) documented by peritoneal fluid containing a neutrophil count of at least 250 cells/mm^3.

OR

D. Hepatorenal syndrome (see 105.00C2d) documented by 1, 2, or 3:

1. Serum creatinine elevation of at least 2 mg/dL; or

2. Oliguria with 24-hour urine output less than 1 mL/kg/hr; or

3. Sodium retention with urine sodium less than 10 mEq per liter.

OR

E. Hepatopulmonary syndrome (see 105.00C2e) documented by 1 or 2:

1. Arterial P_aO_2 measured by an ABG test, while at rest, breathing room air, less than or equal to:

a. 60 mm Hg, at test sites less than 3,000 feet above sea level; or

b. 55 mm Hg, at test sites from 3,000 through 6,000 feet above sea level; or

c. 50 mm Hg, at test sites over 6,000 feet above sea level; or

2. Intrapulmonary arteriovenous shunting as shown on contrast-enhanced echocardiography or macroaggregated albumin lung perfusion scan.

OR

F. Hepatic encephalopathy (see 105.00C2f) with documentation of abnormal behavior, cognitive dysfunction, changes in mental status, or altered state of consciousness (for example, confusion, delirium, stupor, or coma), present on two evaluations within a consecutive 12-month period and at least 60 days apart and either 1 or 2:

1. History of transjugular intrahepatic portosystemic shunt (TIPS) or other surgical portosystemic shunt; or

2. One of the following on at least two evaluations at least 60 days apart within the same consecutive 12-month period as in F:

a. Asterixis or other fluctuating physical neurological abnormalities; or

b. EEG demonstrating triphasic slow wave activity; or

c. Serum albumin of 3.0 g/dL or less; or

d. INR of 1.5 or greater.

OR

G. SSA CLD or SSA CLD–P scores (see 105.00C3):

1. For children age 12 or older, two SSA CLD or SSA CLD–P scores of at least 20 within a consecutive 12-month period and at least 60 days apart; or

2. For children who have not attained age 12, one SSA CLD–P score of at least 11.

OR

H. Extrahepatic biliary atresia as diagnosed on liver biopsy or intraoperative cholangiogram (see 105.00C4). Consider under a disability for 1 year following diagnosis; after that, evaluate the residual impairment(s).

105.06 *Inflammatory bowel disease (IBD)* (see 105.00D) documented by endoscopy, biopsy, imaging, or operative findings *and* demonstrated by A or B:

A. Obstruction of stenotic areas (not adhesions) in the small intestine or colon with proximal dilatation, confirmed by imaging or in surgery, requiring two hospitalizations for intestinal decompression or for surgery, within a consecutive 12-month period and at least 60 days apart.

OR

B. Two of the following occurring within a consecutive 12-month period and at least 60 days apart:

1. Clinically documented tender abdominal mass palpable on physical examination with abdominal pain or cramping; or

2. Perineal disease with a draining abscess or fistula; or

3. Need for supplemental daily enteral nutrition via a gastrostomy or daily parenteral nutrition via a central venous catheter (see 105.10 for children who have not attained age 3).

105.07 *Short bowel syndrome (SBS)* (see 105.00E) due to surgical resection of any amount of the small intestine, resulting in dependence on daily parenteral nutrition via a central venous catheter.

105.08 *Growth failure due to any digestive disorder* (see 105.00F), documented by A and B:

A. Chronic nutritional deficiency present on two evaluations within a consecutive 12-month period and at least 60 days apart documented by 1 or 2:

1. Anemia with hemoglobin less than 10.0 g/dL; or

2. Serum albumin of 3.0 g/dL or less.

AND

B. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2,* three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile values in Table I or Table II; or

TABLE I—MALES BIRTH TO ATTAINMENT OF AGE 2

[Third percentile values for weight-for-length]

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.597	64.5	6.132	84.5	10.301
45.5	1.703	65.5	6.359	85.5	10.499
46.5	1.919	66.5	6.584	86.5	10.696
47.5	2.139	67.5	6.807	87.5	10.895
48.5	2.364	68.5	7.027	88.5	11.095
49.5	2.592	69.5	7.245	89.5	11.296
50.5	2.824	70.5	7.461	90.5	11.498
51.5	3.058	71.5	7.674	91.5	11.703
52.5	3.294	72.5	7.885	92.5	11.910
53.5	3.532	73.5	8.094	93.5	12.119
54.5	3.771	74.5	8.301	94.5	12.331
55.5	4.010	75.5	8.507	95.5	12.546
56.5	4.250	76.5	8.710	96.5	12.764
57.5	4.489	77.5	8.913	97.5	12.987
58.5	4.728	78.5	9.113	98.5	13.213
59.5	4.966	79.5	9.313	99.5	13.443
60.5	5.203	80.5	9.512	100.5	13.678
61.5	5.438	81.5	9.710	101.5	13.918
62.5	5.671	82.5	9.907	102.5	14.163
63.5	5.903	83.5	10.104	103.5	14.413

TABLE II—FEMALES BIRTH TO ATTAINMENT OF AGE 2

[Third percentile values for weight-for-length]

Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)	Length (centimeters)	Weight (kilograms)
45.0	1.613	64.5	5.985	84.5	10.071
45.5	1.724	65.5	6.200	85.5	10.270
46.5	1.946	66.5	6.413	86.5	10.469
47.5	2.171	67.5	6.625	87.5	10.670
48.5	2.397	68.5	6.836	88.5	10.871
49.5	2.624	69.5	7.046	89.5	11.074
50.5	2.852	70.5	7.254	90.5	11.278
51.5	3.081	71.5	7.461	91.5	11.484
52.5	3.310	72.5	7.667	92.5	11.691
53.5	3.538	73.5	7.871	93.5	11.901
54.5	3.767	74.5	8.075	94.5	12.112
55.5	3.994	75.5	8.277	95.5	12.326
56.5	4.220	76.5	8.479	96.5	12.541
57.5	4.445	77.5	8.679	97.5	12.760
58.5	4.669	78.5	8.879	98.5	12.981
59.5	4.892	79.5	9.078	99.5	13.205
60.5	5.113	80.5	9.277	100.5	13.431
61.5	5.333	81.5	9.476	101.5	13.661
62.5	5.552	82.5	9.674	102.5	13.895
63.5	5.769	83.5	9.872	103.5	14.132

2. *For children age 2 to attainment of age 18,* three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile value in Table III or Table IV.

TABLE III—MALES AGE 2 TO ATTAINMENT OF AGE 18

[Third percentile values for BMI-for-age]

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.1	14.5	10.11 to 11.2	14.3	14.9 to 14.10	16.1
2.2 to 2.4	14.4	11.3 to 11.5	14.4	14.11 to 15.0	16.2
2.5 to 2.7	14.3	11.6 to 11.8	14.5	15.1 to 15.3	16.3
2.8 to 2.11	14.2	11.9 to 11.11	14.6	15.4 to 15.5	16.4
3.0 to 3.2	14.1	12.0 to 12.1	14.7	15.6 to 15.7	16.5
3.3 to 3.6	14.0	12.2 to 12.4	14.8	15.8 to 15.9	16.6
3.7 to 3.11	13.9	12.5 to 12.7	14.9	15.10 to 15.11	16.7
4.0 to 4.5	13.8	12.8 to 12.9	15.0	16.0 to 16.1	16.8
4.6 to 5.0	13.7	12.10 to 13.0	15.1	16.2 to 16.3	16.9
5.1 to 6.0	13.6	13.1 to 13.2	15.2	16.4 to 16.5	17.0
6.1 to 7.6	13.5	13.3 to 13.4	15.3	16.6 to 16.8	17.1
7.7 to 8.6	13.6	13.5 to 13.7	15.4	16.9 to 16.10	17.2
8.7 to 9.1	13.7	13.8 to 13.9	15.5	16.11 to 17.0	17.3
9.2 to 9.6	13.8	13.10 to 13.11	15.6	17.1 to 17.2	17.4
9.7 to 9.11	13.9	14.0 to 14.1	15.7	17.3 to 17.5	17.5
10.0 to 10.3	14.0	14.2 to 14.4	15.8	17.6 to 17.7	17.6
10.4 to 10.7	14.1	14.5 to 14.6	15.9	17.8 to 17.9	17.7
10.8 to 10.10	14.2	14.7 to 14.8	16.0	17.10 to 17.11	17.8

TABLE IV—FEMALES AGE 2 TO ATTAINMENT OF AGE 18

[Third percentile values for BMI-for-age]

Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI	Age (yrs. and mos.)	BMI
2.0 to 2.2	14.1	10.8 to 10.10	14.0	14.3 to 14.5	15.6
2.3 to 2.6	14.0	10.11 to 11.2	14.1	14.6 to 14.7	15.7
2.7 to 2.10	13.9	11.3 to 11.5	14.2	14.8 to 14.9	15.8
2.11 to 3.2	13.8	11.6 to 11.7	14.3	14.10 to 15.0	15.9
3.3 to 3.6	13.7	11.8 to 11.10	14.4	15.1 to 15.2	16.0
3.7 to 3.11	13.6	11.11 to 12.1	14.5	15.3 to 15.5	16.1
4.0 to 4.4	13.5	12.2 to 12.4	14.6	15.6 to 15.7	16.2
4.5 to 4.11	13.4	12.5 to 12.6	14.7	15.8 to 15.10	16.3
5.0 to 5.9	13.3	12.7 to 12.9	14.8	15.11 to 16.0	16.4
5.10 to 7.6	13.2	12.10 to 12.11	14.9	16.1 to 16.3	16.5
7.7 to 8.4	13.3	13.0 to 13.2	15.0	16.4 to 16.6	16.6
8.5 to 8.10	13.4	13.3 to 13.4	15.1	16.7 to 16.9	16.7
8.11 to 9.3	13.5	13.5 to 13.7	15.2	16.10 to 17.0	16.8
9.4 to 9.8	13.6	13.8 to 13.9	15.3	17.1 to 17.3	16.9
9.9 to 10.0	13.7	13.10 to 14.0	15.4	17.4 to 17.7	17.0
10.1 to 10.4	13.8	14.1 to 14.2	15.5	17.8 to 17.11	17.1
10.5 to 10.7	13.9	.....	.....	.....	.....

105.09 *Liver transplantation* (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

105.10 *Need for supplemental daily enteral feeding via a gastrostomy* (see 105.00H) due to any cause, for children who have not attained age 3; after that, evaluate the residual impairment(s).

105.11 *Small intestine transplantation* (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

105.12 *Pancreas transplantation* (see 105.00G). Consider under a disability for 1 year from the date of the transplant; after that, evaluate the residual impairment(s).

* * * * *

108.00 Skin Disorders

A. *Which skin disorders do we evaluate under these listings?* We use these listings to evaluate skin disorders that result from hereditary, congenital, or acquired pathological processes. We evaluate genetic photosensitivity disorders (108.07), burns (108.08), and chronic conditions of the skin or mucous membranes such as ichthyosis, bullous disease, dermatitis, psoriasis, and hidradenitis suppurativa (108.09).

B. *What are our definitions for the following terms used in this body system?*

1. *Assistive device(s):* An assistive device, for the purposes of these listings, is any device that is used to improve stability, dexterity, or mobility. An assistive device can be hand-held, such as a cane(s), a crutch(es), or a walker; or worn, such as a prosthesis or an orthosis.

2. *Chronic skin lesions:* Chronic skin lesions can have recurrent exacerbations. They can occur despite prescribed medical treatment. These chronic skin lesions can develop on any part of your body, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Chronic skin lesions may result in functional limitations as described in 108.00D2.

3. *Contractures:* Contractures are permanent fibrous scar tissue resulting in tightening and thickening of skin that prevents normal movement of the damaged area. They can develop on any part of your musculoskeletal system, including upper extremities, lower extremities, palms of your hands, soles of your feet, the perineum, inguinal (groin) region, and axillae (underarms). Contractures may result in functional limitations as described in 108.00D2.

4. *Documented medical need:* When we use the term ''documented medical need,'' we mean that there is evidence from your medical source(s) in the medical record that supports your need for an assistive device (see § 416.913 of this chapter). The evidence must include documentation from your medical source(s) describing any limitation(s) in your upper or lower extremity functioning

that supports your need for the assistive device, and describing the circumstances for which you need it. The evidence does not have to include a specific prescription for the device.

5. *Fine and gross movements:* Fine movements, for the purposes of these listings, involve use of your wrists, hands, and fingers; such movements include picking, pinching, manipulating, and fingering. Gross movements involve use of your shoulders, upper arms, forearms, and hands; such movements include handling, gripping, grasping, holding, turning, and reaching. Gross movements also include exertional activities such as lifting, carrying, pushing, and pulling. Evaluation of fine and gross movements is dependent on your age.

6. *Surgical management:* For the purposes of these listings, surgical management includes the surgery(-ies) itself, as well as various post-surgical procedures, surgical complications, infections or other medical complications, related illnesses, or related treatments that delay a person's attainment of maximum benefit from surgery.

C. *What evidence do we need to evaluate your skin disorder?*

1. To establish the presence of a skin disorder as a medically determinable impairment, we need objective medical evidence from an acceptable medical source who has examined you for the disorder.

2. We will make every reasonable effort to obtain your medical history, treatment records, and relevant laboratory findings, but we will not purchase genetic testing.

3. When we evaluate the presence and severity of your skin disorder(s), we generally need information regarding:

a. The onset, duration, and frequency of exacerbations;

b. The prognosis of your skin disorder;

c. The location, size, and appearance of lesions and contractures;

d. Your history of familial incidence; exposure to toxins, allergens or irritants; seasonal variations; and stress factors;

e. Your ability to function outside of a highly protective environment;

f. Laboratory findings (for example, a biopsy obtained independently of Social Security disability evaluation or results of blood tests);

g. Evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice; and

h. Statements you or others make about your disorder(s), your restrictions, and your daily activities.

D. *How do we evaluate the severity of skin disorders?*

1. *General.* We evaluate the severity of skin disorders based on the site(s) of your chronic skin lesions or contractures, functional limitations caused by your signs and symptoms (including pain) (see 108.00D2), and how your prescribed treatment affects you. We consider the frequency and severity of your exacerbations, how quickly they resolve, and how you function between exacerbations, to determine whether your skin disorder meets or medically equals a listing. If there is no record of ongoing medical treatment for your disorder, we will follow the guidelines in 108.00D6. We will determine the extent and kinds of evidence we need from medical and non-medical sources based on the individual facts about your disorder. For our basic rules on evidence, see §§ 416.912, 416.913, and 416.920b of this chapter. For our rules on evaluating your symptoms, see § 416.929 of this chapter.

2. *Limitation(s) of physical functioning due to skin disorders.*

a. Skin disorders may be due to chronic skin lesions (see 108.00B2) or contractures (see 108.00B3), and may cause pain or restrict movement, which can limit your ability to initiate, sustain, and complete age-appropriate activities. For example, skin lesions in the axilla may limit your ability to raise or reach with the affected arm, or lesions in the inguinal region may limit your ability to ambulate, sit, or lift and carry. To evaluate your skin disorder(s) under 108.07B, 108.08, and 108.09, we require medically documented evidence of physical limitation(s) of functioning related to your disorder. The decrease in physical function must have lasted, or can be expected to last, for a continuous period of at least 12 months (see § 416.909 of this chapter). Xeroderma pigmentosum is the only skin disorder that does not include functional criteria because the characteristics and severity of the disorder itself are sufficient to meet the criteria in 108.07A.

b. The functional criteria require impairment-related physical limitations in using upper or lower extremities that have lasted, or can be expected to last, for a continuous period of at least 12 months, medically documented by one of the following:

(i) Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements;

(ii) Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements due to chronic skin lesions or contractures, and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

(iii) Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

(iv) Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

3. *Frequency of exacerbations due to chronic skin lesions.* A skin disorder resulting in chronic skin lesions (see 108.00B2) may have frequent exacerbations severe enough to meet a listing even if each individual skin lesion exacerbation did not last for an extended amount of time. We will consider the frequency, severity, and duration of skin lesion exacerbations; how quickly they resolve; and how you function in the time between skin lesion exacerbations, to determine whether your skin disorder meets or medically equals a listing.

4. *Symptoms (including pain).* Your symptoms may be an important factor in our determination of whether your skin disorder(s) meets or medically equals a listing. We consider your symptoms only when you have a medically determinable impairment(s) that could reasonably be expected to produce the symptoms. See § 416.929 of this chapter.

5. *Treatment.*

a. *General.* Treatments for skin disorders may have beneficial or adverse effects, and responses to treatment vary from person to person. Your skin disorder's response to treatment may vary due to treatment resistance or side effects that can result in functional limitations. We will evaluate all of the effects of treatment (including surgical treatment, medications, and therapy) on the symptoms, signs, and laboratory findings of your skin disorder, and on your ability to function.

b. *Despite adherence to prescribed medical treatment for 3 months.* Under 108.09, we require that your symptoms persist ''despite adherence to prescribed medical treatment for 3 months.'' This requirement means that you must have taken prescribed medication(s) or followed other medical treatment prescribed by a physician for 3 consecutive months. Treatment or effects of treatment may be temporary. In most cases, sufficient time must elapse to allow us to evaluate your response to treatment, including any side effects. For our purposes, ''sufficient time'' means a period of at least three months. If your treatment has not lasted for at least 3 months, we will follow the rules in 108.00D6a. To evaluate the severity of physical limitations due to your skin disorder(s), we require medically documented evidence of disorder-related physical limitation(s) of functioning that has lasted, or can be expected to last, for a continuous period of at least 12 months. See § 416.909 of this chapter. The 3 months adherence to prescribed medical treatment must be within the period of at least 12 months that we use to evaluate severity.

c. *Treatment with PUVA (psoralen and ultraviolet A (UVA) light) or biologics.* If you receive additional treatment with PUVA or biologics to treat your skin disorder(s), we will defer adjudication of your claim for 6 months from the start of treatment with PUVA or biologics to evaluate the effectiveness of these treatments unless we can make a fully favorable determination or decision on another basis.

6. *No record of ongoing treatment.*

a. Despite having a skin disorder, you may not have received ongoing treatment, may have just begun treatment, may not have access to prescribed medical treatment, or may not have an ongoing relationship with the medical community. In any of these situations, you will not have a longitudinal

medical record for us to review when we evaluate your disorder. In some instances, we may be able to assess the severity and duration of your skin disorder based on your medical record and current evidence alone. We may ask you to attend a consultative examination to determine the severity and potential duration of your skin disorder (see § 416.919a of this chapter).

b. If, for any reason, you have not received treatment, your skin disorder cannot meet the criteria for 108.09. If the information in your case record is not sufficient to show that you have a skin disorder that meets the criteria of one of the skin disorders listings, we will follow the rules in 108.00I.

E. *How do we evaluate genetic photosensitivity disorders under 108.07?* Genetic photosensitivity disorders are disorders of the skin caused by an increase in the sensitivity of the skin to sources of ultraviolet light, including sunlight.

1. *Xeroderma pigmentosum (XP) (108.07A).* XP is a genetic photosensitivity disorder with lifelong hypersensitivity to all forms of ultraviolet light. Laboratory testing confirms the diagnosis by documenting abnormalities in the body's ability to repair DNA (deoxyribonucleic acid) mutations after ultraviolet light exposure. Your skin disorder meets the requirements of 108.07A if you have clinical and laboratory findings supporting a diagnosis of XP (see 108.00E3).

2. *Other genetic photosensitivity disorders (108.07B).* The effects of other genetic photosensitivity disorders may vary and may not persist over time. To meet the requirements of 108.07B, a genetic photosensitivity disorder other than XP must be established by clinical and laboratory findings (see 108.00C) and either must result in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that result in functional limitations (108.00D), or must result in the inability to function outside of a highly protective environment. Some genetic photosensitivity disorders can have very serious effects on other body systems, especially special senses and speech, neurological, mental, and cancer. We will evaluate your disorder(s) under the listings in 102.00, 111.00, 112.00, or 113.00, as appropriate.

3. *What evidence do we need to document that you have XP or another genetic photosensitivity disorder?* We will make a reasonable effort to obtain evidence of your disorder(s), but we will not purchase genetic testing. When the results of genetic tests are part of the existing evidence in your case record, we will evaluate the test results with all other relevant evidence. We need the following clinical and laboratory findings to document that you have XP or another genetic photosensitivity disorder:

a. A laboratory report of a definitive genetic laboratory test documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder, signed by an acceptable medical source (AMS); or

b. A laboratory report of a definitive test that is not signed by an AMS, and a report from an AMS stating that you have undergone definitive genetic laboratory studies documenting appropriate chromosomal changes, including abnormal DNA repair or another DNA abnormality specific to your type of photosensitivity disorder; or

c. If we do not have a laboratory report of a definitive test, we need documentation from an AMS that an appropriate laboratory analysis or other diagnostic method(s) confirms a positive diagnosis of your skin disorder. This documentation must state that you had the appropriate definitive laboratory test(s) for diagnosing your disorder and provide the results, or explain how another diagnostic method(s), consistent with the prevailing state of medical knowledge and clinical practice, established your diagnosis.

4. *Inability to function outside of a highly protective environment* means that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from similar unshielded light sources), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects.

F. *How do we evaluate burns under 108.08?*

1. Electrical, chemical, or thermal burns frequently affect other body systems; for example, *musculoskeletal, special senses and speech, respiratory, cardiovascular, genitourinary, neurological,* or *mental.* We evaluate burns in the same way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your disorder. For example, if your soft tissue injuries resulting from burns are under surgical management (as defined in 108.00B6), we will evaluate your disorder under the listings in 101.00.

2. We evaluate third-degree burns resulting in contractures (see 108.00B3) that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and therefore are no longer receiving surgical management, under 108.08. To be disabling, these burns must result in functional limitation(s) (see 108.00D2) that has lasted or can be expected to last for a continuous period of at least 12 months.

G. *How do we evaluate chronic conditions of the skin or mucous membranes under 108.09?* We evaluate skin disorders that result in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) under 108.09. These disorders must result in chronic skin lesions or contractures that continue to persist despite adherence to prescribed medical treatment for 3 months (see 108.00D5b) and cause functional limitations (see 108.00D2). Examples of skin disorders evaluated under this listing are ichthyosis, bullous diseases (such as pemphigus, epidermolysis bullosa, and dermatitis herpetiformis), chronic skin infections, dermatitis, psoriasis, and hidradenitis suppurativa.

H. *How do we evaluate disorders in other body systems that affect the skin?* When your disorder(s) in another body system affects the skin, we first evaluate the predominant feature of your disorder(s) under the appropriate body system. Examples of disorders in other body systems that affect the skin include the following:

1. *Tuberous sclerosis.* The predominant functionally limiting features of tuberous sclerosis are seizures and intellectual disability or other mental disorders. We evaluate these features under the listings in 111.00 or 112.00, as appropriate.

2. *Malignant tumors of the skin.* Malignant tumors of the skin (for example, malignant melanomas) are cancers, or malignant neoplastic diseases, that we evaluate under the listings in 113.00.

3. *Immune system disorders.* We evaluate skin manifestations of immune system disorders such as systemic lupus erythematosus, scleroderma, psoriasis, and human immunodeficiency virus (HIV) infection under the listings in 114.00.

4. *Head or facial disfigurement or deformity, and other physical deformities caused by skin disorders.* A head or facial disfigurement or deformity may result in loss of your sight, hearing, speech, or ability to chew. In addition to head and facial disfigurement and deformity, other physical deformities may result in associated psychological problems (for example, depression). We evaluate the effects of head or facial disfigurement or deformity, or other physical deformities caused by skin disorders under the listings in 101.00, 102.00, 105.00, or 112.00, as appropriate.

5. *Porphyria.* We evaluate erythropoietic protoporphyria under the listings in 107.00.

6. *Hemangiomas.* We evaluate hemangiomas associated with thrombocytopenia and hemorrhage (for example, Kasabach-Merritt syndrome) involving coagulation defects under the listings in 107.00. When hemangiomas impinge on vital structures or interfere with functioning, we evaluate their primary effects under the listings in the appropriate body system.

I. *How do we evaluate skin disorders that do not meet one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to result in marked and severe limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See § 416.926 of this chapter. If your impairment(s) does not meet or medically equal a listing, we will also consider whether your impairment(s) functionally equals the listings. See § 416.926a of this chapter. We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

108.01 Category of Impairments, Skin Disorders

108.02–108.06 [Reserved]

108.07 *Genetic photosensitivity disorders,* established as described in 108.00E. The requirements of this listing are met if either paragraph A or paragraph B is satisfied.

A. Xeroderma pigmentosum (see 108.00E1).

OR

B. Other genetic photosensitivity disorders (see 108.00E2) with either 1 or 2:

1. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause an

inability to function outside of a highly protective environment (see 108.00E4); or

2. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause functional limitations (see 108.00D2) due to limitation(s) from your skin condition, such as pain, as evidenced by:

a. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements; or

b. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

c. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

d. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

108.08 *Burns* (see 108.00F). Third-degree burns that do not require continuing surgical management, or that have been documented by an acceptable medical source to have reached maximum therapeutic benefit and are no longer receiving surgical management, resulting in chronic skin lesions (see 108.00B2) or contractures (see 108.00B3) that cause functional limitations (see 108.00D2) due to limitation(s), such as pain, from your skin condition, as evidenced by:

A. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements.

OR

B. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity.

OR

C. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

OR

D. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

108.09 *Chronic conditions of the skin or mucous membranes* (see 108.00G) resulting in:

A. Chronic skin lesions (see 108.00B2) or contractures (see 108.00B3); chronic pain; or other physical limitation(s); that persist despite adherence to prescribed medical treatment for 3 months (see 108.00D5b), causing functional limitations (see 108.00D2) due to limitation(s), such as pain, from your skin condition.

AND

B. Impairment-related significant limitation demonstrated by 1, 2, 3, or 4:

1. Inability to use both upper extremities to the extent that neither can be used to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements; or

2. Inability to use one upper extremity to independently initiate, sustain, and complete age-appropriate activities involving fine and gross movements (due to chronic skin lesions or contractures), and a documented medical need for a one-handed assistive device that requires the use of your other upper extremity; or

3. Inability to stand up from a seated position and maintain an upright position to the extent you can independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting at least two extremities (including when the limitations are due to involvement of the perineum or the inguinal region); or

4. Inability to maintain an upright position while standing or walking, to independently initiate, sustain, and complete age-appropriate activities due to chronic skin lesions or contractures affecting both lower extremities (including when the limitations are due to involvement of the perineum or the inguinal region).

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Title 3—

The President

Proclamation 9910 of July 19, 2019

Captive Nations Week, 2019

By the President of the United States of America

A Proclamation

The United States has always been a source of hope to people around the world fighting to replace tyranny with liberty, justice, and the rule of law. During Captive Nations Week, we reaffirm our Nation's unwavering support for those who strive to be free from oppression. We condemn repressive regimes that deny people their God-given rights, including life, liberty, and the pursuit of happiness.

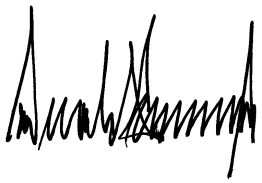
President Dwight D. Eisenhower first proclaimed Captive Nations Week in 1959, when freedom in the United States was a bulwark against the totalitarianism of communist regimes in Eastern Europe and elsewhere. Even today, many decades since the end of the Cold War unleashed a new era of democratic flourishing, tyrannical and coercive governments still threaten the freedom and well-being of countless individuals worldwide. They persecute people for worshiping their God, and jail people for daring to speak out and for demanding even the most basic forms of transparency and accountability. They use food distribution as a tool of social control, manipulate electoral processes, and undermine the will and spirit of their people through intimidation and fear. The United States stands with repressed people around the world and urges governments everywhere to respect the God-given rights of every individual and to embrace the establishment of representative government.

As Americans, we are privileged and blessed to live in a Nation in which our Constitution protects fundamental rights like freedom of expression, association, religion, and peaceful assembly. We will continue to advocate for those who are unjustly denied these and other rights, and stand against brutality and oppression, which violate the dignity of all people.

The Congress, by Joint Resolution approved July 17, 1959 (73 Stat. 212), has authorized and requested the President to issue a proclamation designating the third week of July of each year as ''Captive Nations Week.''

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 21 through July 27, 2019, as Captive Nations Week. I call upon all Americans to reaffirm our commitment to supporting those around the world striving for liberty, justice and the rule of law.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of July, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–15989
Filed 7–24–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9911 of July 19, 2019

50th Anniversary Observance of the Apollo 11 Lunar Landing

By the President of the United States of America

A Proclamation

In 1961, President John F. Kennedy boldly challenged our Nation to land an American on the Moon and return him safely to Earth within that decade. Eight years later, thanks to the spirit, pride, tenacity, and expertise of scientists, engineers, aviators, and visionaries, America completed this remarkable feat in human space exploration. On the 50th anniversary of this historic milestone, we honor the brave astronauts of the Apollo 11 spaceflight and all the men and women whose sacrifices, unwavering dedication, and extraordinary talent produced one of history's most triumphant achievements.

On July 16, 1969, families and communities around the world watched in awe and trepidation as a trio of astronauts—Neil Armstrong, Buzz Aldrin, and Michael Collins—climbed into the command module Columbia and left Earth on the first manned mission to land on the Moon. The intrepid pilots traveled nearly a quarter of a million miles through space, and 4 days later, on July 20, 1969, they landed the Apollo 11 lunar module on the Moon's Sea of Tranquility.

Neil Armstrong's first steps on the Moon brought humanity into a new era. And as he and Buzz Aldrin planted the American flag into the ''magnificent desolation'' of the Moon's surface, they left no doubt about what had brought humans to the new frontier—American ingenuity, grit, and determination.

Apollo 11 fueled advancements in many sectors of our society, including science, technology, and commerce. And the work of the National Aeronautics and Space Administration (NASA) and the entire aerospace industry remains critical to our Nation's continued quest for greatness, powers our economy, and strengthens our defense.

Early in my Administration, I pledged to renew America's commitment to human space exploration and the boundless potential beyond Earth's gravity. I revived the National Space Council within the White House to coordinate all space-related activities across the Government, including with the National Security Council on matters relating primarily to national security. The Space Council has helped to bring together skilled leaders in business and industry to accelerate innovation and seize opportunities throughout the space enterprise. I also signed Space Policy Directive–1, challenging NASA to lead the return of Americans to the Moon, eventually send the first Americans to Mars, and enable humans to expand and deepen our reach across the solar system.

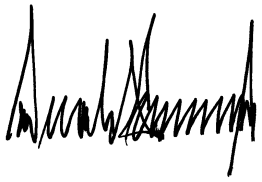
As Neil Armstrong's boots pressed into the dust on the Moon's surface in 1969, he delivered an unforgettable message, ''one small step for man, one giant leap for mankind.'' His words have resonated around the globe and through the years to embolden dreamers and future explorers and to draw their attention to the power and the possibility of the boundless wonders of space. Today, we reaffirm our continuing and shared quest

to unlock greater mysteries, take bigger leaps for humanity, and advance America's leadership in space exploration.

The success of Apollo 11 is one of our country's defining moments. As we observe this 50th anniversary of the first lunar landing, we celebrate the incredible voyage of our Nation's heroic astronauts, and all those who supported them from mission control and elsewhere back home. Their historic accomplishment rallies our patriotism and pride, ignites our sense of adventure, and steels our belief that no dream is impossible—no matter how lofty or challenging.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 20, 2019, as the 50th Anniversary Observance of the Apollo 11 Lunar Landing. I call upon public officials, educators, and all Americans to observe this occasion by honoring the Apollo 11 mission and all of the men and women who have served in our Nation's space program.

IN WITNESS WHEREOF, I have hereunto set my hand this nineteenth day of July, in the year of our Lord two thousand nineteen, and of the Independence of the United States of America the two hundred and forty-fourth.



[FR Doc. 2019–15991
Filed 7–24–19; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Presidential Determination No. 2019–15 of July 22, 2019

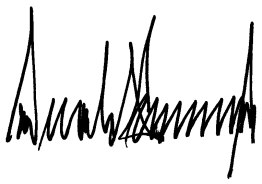
Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that the domestic manufacturing capability for F135 Integrally Bladed Rotors is essential to the national defense.

Without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the production capability for manufacturing F135 Integrally Bladed Rotors adequately and in a timely manner. Further, purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need for this critical capability.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2019

[FR Doc. 2019–15994
Filed 7–24–19; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Presidential Determination No. 2019–16 of July 22, 2019

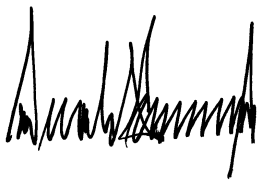
Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that the domestic production capability for separation and processing of Heavy Rare Earth Elements is essential to the national defense.

Without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the production capability for separation and processing of Heavy Rare Earth Elements adequately and in a timely manner. Further, purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need for this critical capability.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2019

[FR Doc. 2019–15995
Filed 7–24–19; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Presidential Determination No. 2019–17 of July 22, 2019

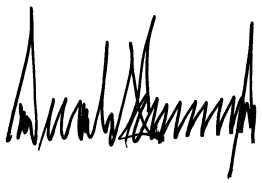
Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that the domestic production capability for separation and processing of Light Rare Earth Elements is essential to the national defense.

Without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the production capability for separation and processing of Light Rare Earth Elements adequately and in a timely manner. Further, purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need for this critical capability.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2019

[FR Doc. 2019–15998
Filed 7–24–19; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Presidential Determination No. 2019–18 of July 22, 2019

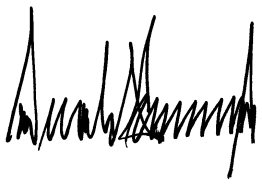
Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that the domestic production capability for Rare Earth Metals and Alloys is essential to the national defense.

Without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the production capability for Rare Earth Metals and Alloys adequately and in a timely manner. Further, purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need for this critical capability.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2019

[FR Doc. 2019–15999
Filed 7–24–19; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Presidential Determination No. 2019–19 of July 22, 2019

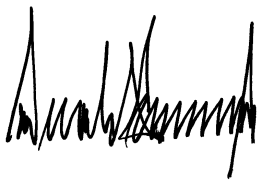
Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that the domestic production capability for Neodymium Iron Boron Rare Earth Sintered Material and Permanent Magnets is essential to the national defense.

Without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the production capability for Neodymium Iron Boron Rare Earth Sintered Material and Permanent Magnets adequately and in a timely manner. Further, purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need for this critical capability.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2019

[FR Doc. 2019–16001
Filed 7–24–19; 11:15 am]
Billing code 5001–06–P

Presidential Documents

Presidential Determination No. 2019–20 of July 22, 2019

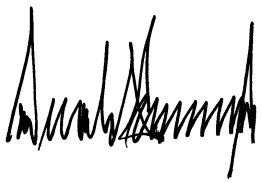
Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the ''Act'') (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that the domestic production capability for Samarium Cobalt Rare Earth Permanent Magnets is essential to the national defense.

Without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide the production capability for Samarium Cobalt Rare Earth Permanent Magnets adequately and in a timely manner. Further, purchases, purchase commitments, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative method for meeting the need for this critical capability.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, July 22, 2019

[FR Doc. 2019–16002
Filed 7–24–19; 11:15 am]
Billing code 5001–06–P

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Federal Register

Vol. 84, No. 143

Thursday, July 25, 2019

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FEDERAL REGISTER PAGES AND DATE, JULY

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

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